**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**

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| PHYSEON GmbH,<br><br>Plaintiff,<br><br>v.<br><br>COVANCE INC.,<br><br>Defendant. | Court File No. 0:20-cv-00758 (WMW/BRT)<br><br>**DEFENDANT'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT AND COUNTERCLAIM**<br><br>**JURY TRIAL DEMAND** |

Defendant Covance Inc. ("Covance" or "Defendant"), by and for its Answer and Affirmative Defenses to Plaintiff's Complaint, states and alleges as follows:

## ANSWER

Covance denies each and every allegation, matter, and thing contained in Plaintiff's Complaint, unless hereinafter specifically admitted or otherwise qualified.

Titles, header, paragraph, or section descriptions and allegations contained in the Complaint are repeated herein for ease of reference, and no admission to their accuracy is made by such inclusion.

## "NATURE OF THE ACTION"

1. This matter arises out of RCRI's failure to properly manage and oversee a critically important clinical trial for a new medical device, Veinplicity®. Veinplicity® was developed by Physeon to safely increase blood flow and stabilize peripheral veins in the forearm to improve the rate of successful venipuncture and cannulation in patients. Physeon entrusted RCRI with this clinical trial, which was crucial to Veinplicity® gaining marketing approval in the United States from the United

States Food and Drug Administration ("FDA"). Physeon contracted with RCRI because RCRI touted itself as being an expert and "leading clinical research organization" that could help design, administer, manage, and analyze clinical trials and clinical trial results to maximize the chances of regulatory approval.

**ANSWER:** Paragraph 1 of Plaintiff's Complaint violates the requirement of Fed. R. Civ. P. 8(d)(1) that "[e]ach allegation must be simple, concise, and direct." Without waiving that objection, Covance admits that RCRI, merged into Covance since December 31, 2019, was at all relevant times an expert and "leading clinical research organization." Covance denies that RCRI failed to properly manage or oversee the clinical trial for the Veinplicity® medical device. Covance cannot speak to the remaining allegations contained in Paragraph 1 of the Complaint, and accordingly denies and puts Plaintiff to its strict proof thereof.

2. RCRI agreed to ensure that the clinical trial of Veinplicity® would comply with, among other standards, ethical and quality standards, U.S. regulations governing the conduct of clinical trials, and the specific protocol and related procedures that it prepared for the Veinplicity® clinical trial. RCRI knew that adherence to these standards and the protocol was of critical importance not only to meet its own contractual duties to Physeon, but also to meet the standards of the regulatory authorities (namely, the FDA) and the ethical and protocol controls enforced by the clinical sites' Institutional Review Boards ("IRBs"). RCRI, however, completely failed to perform its obligations in accordance with its agreement with Physeon and

the applicable regulatory, industry and ethical standards. In fact, RCRI completely failed in its obligation to monitor and supervise the clinical sites to ensure protocol compliance and accurate data collection. In so doing, RCRI undermined the validity of the clinical trial — rendering it worthless — which resulted in the Veinplicity® trial incorrectly and prematurely being deemed a failure. Because RCRI failed to ascertain the reason for the failure (i.e. that clinicians were not following the written protocol for the study) and never reported non-compliance with the protocol to Physeon, Physeon and RCRI prematurely stopped the trial and closed clinical sites, likely preventing Physeon from being able to obtain marketing authorization for Veinplicity® in the United States. Physeon brings this action to recover damages and other relief as a result of RCRI's breach of the parties' agreement, its improper and deceptive acts, and breach of its express and implicit obligations to regulatory authorities, the IRBs, and the patients.

**ANSWER:** Paragraph 2 of Plaintiff's Complaint violates the requirement of Fed. R. Civ. P. 8(d)(1) that "[e]ach allegation must be simple, concise, and direct." Without waiving that objection, Covance answers that RCRI's work under its contract with Plaintiff was performed in full compliance with ethical and quality standards, the applicable regulations, and the protocol established for the Veinplicity® clinical trial and in accordance with its obligations under the contract. Covance denied that RCRI "failed to perform its obligations in accordance with its agreement with Physeon and the applicable regulatory, industry and ethical standards." Covance further

denies that "In fact, RCRI completely failed in its obligation to monitor and supervise the clinical sites to ensure protocol compliance and accurate data collection." Covance furthermore denies that "RCRI undermined the validity of the clinical trial — rendering it worthless — which resulted in the Veinplicity® trial incorrectly and prematurely being deemed a failure." Covance also denies that "clinicians were not following the written protocol for the study," rendering the allegations that RCRI failed to report "non-compliance with the protocol to Physeon" devoid of an underlying factual basis. Covance admits that "Physeon brings this action to recover damages and other relief," but denies that Physeon is entitled to damages, denies that the parties' agreement provides for unspecified "other relief," and accordingly seeks entry of judgment in its favor. Covance denies all other and further allegations contained in Paragraph 2 of the Complaint.

**"The Parties"**

3. Plaintiff Physeon is a corporation organized and existing under the laws of Switzerland, with its principal place of business in Schaffhausen, Switzerland. Plaintiff has operations in the United States, including in the State of Minnesota.

**ANSWER:** Upon information and belief, Covance admits the allegations contained Paragraph 3 of the Complaint with respect to the time of the parties' agreement. Covance has no knowledge about Plaintiff's current operations in the United States and in the State of Minnesota, and puts Plaintiff to its strict proof thereof.

4. Defendant Covance Inc. is a Delaware corporation with its principal place of business and executive offices at 210 Carnegie Cir., Princeton, New Jersey 08540. Covance Inc. maintains an address in Minnesota at 2345 Rice Street, Suite 230, Roseville, MN 55113.

**ANSWER:** With respect to the allegations contained in Paragraph 4 of the Complaint, Covance admits that it is a Delaware corporation with its principal place of business and executive offices at 210 Carnegie Cir., Princeton, New Jersey 08540. It denies the remaining allegations, as 2345 Rice Street, Suite 230, Roseville, MN 55113, is the address of its Minnesota registered agent for service of process, Corporation Service Company.

5. Defendant Covance Inc. merged with Regulatory & Clinical Research Institute, Inc. on or about December 31, 2019 with Covance Inc. continuing as the surviving corporation and legal successor in interest. Prior to the merger, Regulatory & Clinical Research Institute, Inc. was a Minnesota corporation with its principal place of business at 5353 Wayzata Boulevard, Suite 505, Minneapolis, Minnesota 55416. On information and belief, Covance Inc. continues to operate Regulatory & Clinical Research Institute from this address (See https://www.rcri-inc.com/).

**ANSWER:** Covance admits the allegations contained in Paragraph 5 of the Complaint.

**"Jurisdiction and Venue"**

6. On or about March 19, 2018, Physeon entered into the Master Services Agreement ("MSA") with RCRI, pursuant to which RCRI agreed to provide regulatory, health

economics and clinical trial consulting and management services to Physeon and to manage the clinical trial set forth in the study protocol ("Protocol") (and incorporated into the MSA) of its Veinplicity® device that ultimately was conducted at clinic sites in Minnesota. See MSA attached as Exhibit "1" and Protocol attached as Exhibit "2."

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 6 of the Complaint that RCRI entered into the MSA attached to the Complaint as Exhibit 1 on March 19, 2018, and affirmatively alleges that Exhibit 1 to the Complaint shows that Physeon's CEO, Patrick C. Kullmann ("Kullmann"), executed the MSA on behalf of Physeon on March 23, 2018. The MSA speaks for itself, and Covance denies all allegations and inferences that are contrary to the MSA, which is an integrated agreement, as set forth in section 12.8 thereof. Covance further admits that the clinical trial was conducted at clinic sites in Minnesota and that the Protocol is attached as Exhibit 2 to the Complaint.

7. This Court has jurisdiction under 28 U.S.C. § 1332 in that the parties are of diverse citizenship and the amount in controversy exceeds $75,000.00. Defendant Covance Inc. is a citizen of Delaware and New Jersey for diversity purposes, and Plaintiff is a citizen of Switzerland.

**ANSWER:** Covance admits the allegations contained in Paragraph 7 of the Complaint.

8. Venue is proper in this federal district pursuant to 28 U.S.C. § 1391 (b)(2) because

a substantial part of the events or omissions giving rise to the claim occurred in this district.

**ANSWER:** Covance admits the allegations contained in Paragraph 8 of the Complaint. Covance further notes that section 12.4 of the MSA provides for personal and exclusive jurisdiction and venue in Minnesota.

9. The MSA further provides that it shall be governed by and construed in accordance with the laws of Minnesota.

**ANSWER:** Covance admits the allegations contained in Paragraph 9 of the Complaint.

**"FACTUAL ALLEGATIONS"**

**"A. Physeon and Its Veinplicity® Device"**

10. Physeon is a medical device company that was established in 2015 to develop and commercialize new innovations in the healthcare industry. Physeon's flagship product is the Veinplicity® device.

**ANSWER:** Covance has no personal knowledge of the allegations contained in Paragraph 10 of the Complaint and accordingly puts Plaintiff to its strict proof thereof.

11. Veinplicity® is an innovative, electrical stimulation device that may be used in adjunct to venipuncture or venous cannulation. Venipuncture is the common procedure of inserting a needle into a vein to draw blood or administer medications. Venous cannulation is the insertion of a temporary indwelling catheter or tube into that vein following such venipuncture to administer fluids or medications on a

longer-term basis (hereinafter, "cannulation").

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 11 of the Complaint that the Veinplicity® device is an electrical stimulation device that Physeon has represented to have the design intent to be an adjunct to venipuncture or venous cannulation, that venipuncture is the common procedure of inserting a needle into a vein to draw blood or administer medications, and that venous cannulation is the insertion of a temporary indwelling catheter or tube into that vein following such venipuncture to administer fluids or medications on a longer-term basis. Covance denies the remaining allegations.

12. Veinplicity® is attached to the forearm via a disposable electrode and emits a gentle electrical current with a specific wave form. Stimulation of the nerves and muscles in the forearm result in increased blood flow and vasodilation, while stimulation of receptors in the vessel wall causes veins to stiffen. Enlarged veins are pushed towards the surface where they are easier to identify and palpate, better anchored and less prone to rolling. This enhances the ability of medical professionals to cannulate forearm veins on the first attempt, which is generally termed "first-stick."

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 12 of the Complaint that the Veinplicity® device was designed to be attached to the forearm via a disposable electrode and to emit an electrical current. Covance further admits that Physeon has represented that the stimulation of the nerves and muscles by the Veinplicity® device was

intended to increase blood flow and vasodilation, to cause veins to stiffen, for enlarged veins to be pushed towards the surface, to be easier to identify and palpate, to be better anchored, and to be less prone to rolling, enhancing the ability of medical professionals to cannulate forearm veins on the first attempt. Covance has no independent data to confirm or refute these design intents, and the United States clinical trial was intended to test whether the Veinplicity® device performed as asserted by Physeon. Covance further admits that the ability of medical professionals to cannulate forearm veins on the first attempt is generally termed "first-stick." Covance denies the remaining allegations contained in Paragraph 12 of the Complaint.

13. Physeon had earlier conducted a clinical trial study in the Netherlands, the results of which were published on March 28, 2019, in the Journal of Vascular Access. The clinical study, authored by Fredericus Loon, et al, [*sic*] titled Clinical Use of Electrical Stimulation with the Veinplicity® Device and its Effect on the First Attempt Success Rate of Peripheral Intravenous Cannulation: A Non-randomized Clinical Trial, demonstrated an overall first-stick or first attempt success rate of 92% using Veinplicity® plus tourniquet for cannulation, as compared with a first-stick success rate of 78% in the control group (tourniquet only). (https://www.ncbi.nlm.nih.gov/pubmed/30919735).

**ANSWER:** Upon information and belief, Covance admits the allegations contained within Paragraph 13 of the Complaint but denies the implicit allegation that the Dutch clinical trial, which was performed on different

study subjects and under a different protocol, was identical or an indication that the outcome of the Dutch clinical trial would be valid in the United States. The FDA's randomized clinical study standards for the Veinplicity® device were materially different and more difficult to meet than the standards employed in the non-randomized Dutch study. The entire purpose of the United States clinical trial was to determine whether Veinplicity® performed as intended under the FDA's more demanding standards. Because the standards were different, any comparison between the Dutch study and the United States study is invalid. Furthermore, the medical science and epidemiologic literature has copious examples of markedly different trial results when nonrandomized trials on a given therapy are compared to those of randomized trials. Biases inherent in nonrandomized trials are discussed in Clinical Trial references (*see, e.g.*, Non-Randomized Trial, Zhengqing Li, 14 December 2007, available with subscription at https://doi.org/10.1002/9780471462422.eoct306).

14. Following the success of its Netherlands clinical trial study, in advance of coming to market in the United States and in order to gain FDA marketing authorization for Veinplicity® as a Class II medical device, Physeon sought to conduct a clinical trial study in the United States to further demonstrate the device's safety and efficacy to the FDA.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 14 of the Complaint that in advance of coming to market in the

United States and in order to gain FDA marketing authorization for Veinplicity® as a Class II medical device, Physeon sought to conduct a clinical trial study in the United States to demonstrate the device's safety and efficacy to the FDA. Covance denies the implicit allegation that the Dutch clinical trial, which was performed on different study subjects and under a different protocol, was identical or an indication that the outcome of the Dutch clinical trial would be valid in the United States. The FDA's randomized clinical study standards for the Veinplicity® device were materially different and more difficult to meet than the standards employed in the non-randomized Dutch study. The entire purpose of the United States clinical trial was to determine whether Veinplicity® performed as intended under the FDA's more demanding standards. Because the standards were different, any comparison between the Dutch study and the United States study is invalid. Furthermore, as also stated above, the medical science and epidemiologic literature has copious examples of markedly different trial results when nonrandomized trials on a given therapy are compared to those of randomized trials. Biases inherent in nonrandomized trials are discussed in Clinical Trial references (*see, e.g.*, Non-Randomized Trial, Zhengqing Li, 14 December 2007, available with subscription at https://doi.org/10.1002/9780471462422.eoct306).

15. Physeon and RCRI on its behalf held meetings with FDA to design a suitable protocol. FDA advised Physeon and RCRI that the Protocol eventually

implemented would support marketing authorization if conducted in accordance with regulations and ethical standards and if the results in terms of safety and first-stick success were comparable to the study in the Netherlands.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 15 of the Complaint that Physeon had meetings with the FDA on its own prior to RCRI's involvement, and that RCRI subsequently became involved and also had interactions with the FDA on Physeon's behalf, which interactions were in writing only. Covance denies the remaining statements.

**"B. RCRI Markets and Holds Itself Out As Being A Leading Clinical Research Organization"**

16. RCRI promotes and holds itself out as being a "leading clinical research organization, medical device consulting firm, and strategic regulatory expert." (website page: https://www.rcri-inc.com/).

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 16 of the Complaint that RCRI's website contains the statement "RCRI is the leading clinical research organization, medical device consulting firm and strategic regulatory expert."

17. In doing so, RCRI promotes its clinical research organization ("CRO") services as being committed to the "highest standards of professional excellence in CRO research and clinical trials." (website page: https://www.rcri-inc.com/clinical-research/).

**ANSWER:** Covance admits with respect to the allegations contained in

Paragraph 17 of the Complaint that RCRI's website contains the statement "At RCRI, we are scientists first — committed to the highest standards of professional excellence in CRO research and clinical trials. There are some CROs that have been around for a while, but none that have also delivered the most accurate, efficient, and sophisticated clinical research consulting services PLUS an integrated consulting partnership since 1999 like RCRI."

18. In fact, RCRI acknowledges that the "success of a clinical trial" requires a "focus on flawless execution," and represents to the public that its ability to provide "flawless execution" of clinic trial protocols is the reason why "[its] studies generate compelling evidence." (Id.)

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 18 of the Complaint that RCRI's website contains the statement "Maximizing the success of a clinical trial requires an integration of regulatory know-how with business savvy and a focus on flawless execution. As a result, our studies generate compelling evidence demonstrating value for all stakeholders in the timeframe that meets or even beats your schedule." Covance further notes that Physeon expressly agreed in section 9.1 of the MSA that RCRI does not give any warranty as to results, approval, or success of any submissions or the like to regulatory agencies; that RCRI makes no warranty that the services will be error-free; and that any and all other warranties, express or implied, regarding the services or any results, including, without limitation, the implied warranties of merchantability and

fitness for a particular purpose, and any warranties with respect to the quality, content, condition, or use of results, were expressly disclaimed, which disclaimers Physeon agreed to, in writing.

19. RCRI further represents, promotes, and markets its ability during clinical trials to "quickly pinpoint areas for improvement or efficiency, [and] identify unusual findings in the data," which allows its clients to obtain clinical evidence in support of their medical products. (Id.) Unlike drug trials, studies of medical devices are not generally blinded, which permits, real-time analysis of study management, study data, and any other implementation issues that might otherwise bar such "flawless execution."

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 19 of the Complaint that RCRI's website contains the statement "An experienced team makes all the difference in the success of your study. Our advisors' breadth of expertise covers medical device clinical strategy, trial design, operationalization, data management, clinical compliance, biostatistics and medical writing. Using our deep experience in both premarket and post market studies, we can quickly pinpoint areas for improvement or efficiency, identify unusual findings in the data, and work with you to anticipate and overcome challenges, while obtaining the necessary evidence at the right time in your product lifecycle." Covance denies the allegation in Paragraph 19 of the Complaint that "Unlike drug trials, studies of medical devices are not generally blinded, which permits,

real-time analysis of study management, study data, and any other implementation issues that might otherwise bar such 'flawless execution.'" Not only is this statement not found on RCRI's website, but studies of many medical devices are, in fact, blind. For example, an implantable device may be turned on or off, without the medical team knowing whether the device is on or off. Furthermore, improvement and efficiency pinpointing does not mean conducting mid-trial data analyses to determine the efficacy of the device subject to the clinical trial. To the extent Physeon suggests that RCRI should have conducted data analyses during the clinical trial different from those pre-specified in the Protocol, Covance denies the allegation. The FDA has instructed that "[p]oorly performed, inappropriate, and/or *post-hoc* analyses may adversely affect the usefulness of the evidence to support the safety and effectiveness of a device. Thus, the study protocol should have a detailed, pre-specified Statistical Analysis Plan [SAP] that includes plans to evaluate, to the extent possible, key assumptions that were made in the design of the study (e.g., assessment of carry-over effects in a crossover study design, proportionality of hazards in a survival analysis, or pooling analysis across clinical sites or geographic regions). This predefined SAP should be adhered to in analyzing the data at the completion of the study to support the usefulness of the evidence generated by the study. ***Unplanned* post-hoc *analyses and deviation from the analysis populations specified in the protocol should generally be avoided. Examples of* post-hoc *analyses***

***include the use of a different statistical analysis without proper justification, change in the primary endpoint, or the use of a subgroup for analysis that was not pre-specified***." U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health and Center for Biologic Evaluation and Research, *Design Considerations for Pivotal Clinical Investigations for Medical Devices: Guidance for Industry, Clinical Investigators, Institutional Review Boards and Food and Drug Administration Staff* 49 (Nov. 7, 2013) (emphasis added) (copy available at https://www.fda.gov/media/87363/download). Furthermore, any suggestion that a sub-analysis may be performed, such as Physeon claims to have performed after July 12, 2019, is in direct conflict with the biostatistical principle of analysis per "Intention to Treat." The handpicking of data after the fact in an attempt to find the best possible outcome is considered unscientific and is discredited by the scientific community. Thus, the FDA's Centers for Drug Evaluation and Research (CDER) and Biologics Evaluation and Research (CBER) have warned that "[p]reservation of the initial randomization in analysis is important in preventing bias and in providing a secure foundation for statistical tests." E9 Statistical Principles for Clinical Trials (Sept. 1998) (ICH) (copy available at https://www.fda.gov/media/71336/download).

20. RCRI further lists its capabilities as including clinical study operations, site management and site monitoring services, and regulatory and ethical compliance,

monitoring of clinical study sites and auditing. (Id.)

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 20 of the Complaint that RCRI's website lists among its capabilities "clinical study operations," "site management," "site monitoring services," "clinical compliance/auditing," "regulatory compliance consulting," and "regulatory strategy." Covance denies the remaining allegations contained in Paragraph 20 of the Complaint.

21. RCRI also directly promoted its experience to Physeon. RCRI represented to Physeon that it was one of only a few ISO 9001:2008 certified medical device CROs in the world and that its established "quality system" would ensure any clinical trial carried out for Physeon would be done using "well-proven processes."

**ANSWER:** Covance admits the allegations contained in Paragraph 21 of the Complaint. Covance also notes that RCRI's contractual obligations are set forth in the MSA, which is an integrated agreement as set forth in section 12.8 thereof, and that any other information considered by Physeon is expressly excluded from the terms of the parties' agreement, and could not be relied upon by Physeon.

22. RCRI represented to Physeon that it had a "significant and proven track record in the neuromodulation and venous areas," and that it had engaged in hundreds of clinical trials across a wide range of therapeutic areas, including medical technology and novel therapies. RCRI also represented that its consultants specialize in medical device studies.

**ANSWER:** Covance admits the allegations contained in Paragraph 22 of the Complaint. Covance also notes that RCRI's contractual obligations are set forth in the MSA, which is an integrated agreement as set forth in section 12.8 thereof, and that any other information considered by Physeon is expressly excluded from the terms of the parties' agreement, and could not be relied upon by Physeon.

23. In addition, RCRI represented that its relationships with clinical sites, based on their long history and experience, would enable RCRI to identify and enlist clinical sites qualified to perform Physeon's study rapidly and efficiently.

**ANSWER:** Covance admits the allegations contained in Paragraph 23 of the Complaint. Covance also notes that RCRI's contractual obligations are set forth in the MSA, which is an integrated agreement as set forth in section 12.8 thereof, and that any other information considered by Physeon is expressly excluded from the terms of the parties' agreement, and could not be relied upon by Physeon.

**"C. Physeon Hires RCRI To Conduct Its "VIVA" Clinical Trial Study"**

24. Based on RCRI's representations to Physeon regarding its CRO capabilities and expertise, including that it could flawlessly execute clinical trial protocols and manage and monitor clinical trial sites for compliance with regulations and protocols, Physeon entered a written contract with RCRI to conduct a clinical trial study in the United States with respect to Veinplicity®.

**ANSWER:** Covance cannot speak to the allegations contained in Paragraph

24 of the Complaint, and accordingly denies and puts Plaintiff to its strict proof thereof. Covance also notes that RCRI's contractual obligations are set forth in the MSA, which is an integrated agreement as set forth in section 12.8 thereof, and that any other information considered by Physeon is expressly excluded from the terms of the parties' agreement, and could not be relied upon by Physeon.

25. On or about March 18, 2018, Physeon and RCRI entered into the MSA pursuant to which RCRI was to perform consulting services for Physeon and run its clinical trial study, pursuant to the written Protocol it developed with input from Physeon entitled the "Veinplicity® for Improved Venous Access" Study, aka the "VIVA Study."

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 25 of the Complaint that RCRI entered into the MSA attached to the Complaint as Exhibit 1 on March 19, 2018, and affirmatively alleges that Exhibit 1 to the Complaint shows that Kullmann executed the MSA on behalf of Physeon on March 23, 2018. The MSA speaks for itself, and Covance denies all allegations and inferences that are contrary to the MSA, which is an integrated agreement, as set forth in section 12.8 thereof. Covance further admits that it developed the written Protocol with significant input from Physeon, that Physeon signed off on every version of the Protocol, that Exhibit 2 to the Complaint is entitled "Veinplicity for Improved Venous Access: The VIVA Trial," and that the Protocol is deliberately titled "Investigational Plan." Covance denies all other and further allegations.

26. RCRI agreed to ensure that the VIVA Study would comply with, among other standards, applicable FDA regulations, local IRB requirements, the approved informed consent, and its own guidelines and standard operating procedures. RCRI knew that adherence to these standards was critical to both its contractual duties to Physeon under the MSA, but also to the public interest in the conduct of ethical medical research, and to meet the standards of the FDA which would eventually audit the clinical sites and evaluate the conduct of the study before accepting the study results.

**ANSWER:** Covance admits the allegations contained in Paragraph 26 of the Complaint. Covance also notes, however, that section 9.1 of the MSA provides that "[Physeon] acknowledges that approvals and clearances of regulatory agencies are subjective and that RCRI does not give any warranty as to results, approval, or success of any submissions or the like to regulatory agencies. RCRI MAKES NO WARRANTY THAT THE SERVICES WILL BE ERROR-FREE. EXCEPT AS EXPRESSLY PROVIDED IN THIS SECTION 9.1, RCRI EXPRESSLY DISCLAIMS, AND [PHYSEON] EXPRESSLY WAIVES, ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, REGARDING THE SERVICES OR ANY RESULTS, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ANY WARRANTIES WITH RESPECT TO THE QUALITY, CONTENT, CONDITION OR USE OF RESULTS, AND

ANY WARRANTY AGAINST INTELLECTUAL PROPERTY INFRINGEMENT OR THE LIKE." (All caps font in original.)

27. The well-understood content of the obligations to which RCRI committed (e.g., monitoring, compliance with regulations governing the conduct of clinical trials, compliance with the Protocol) are set forth in detail in numerous regulations promulgated by FDA, guidance issued by FDA, guidelines of the International Conference on Harmonization adopted by FDA, and in a number of FDA websites (see, e.g., https://www.fda.gov/medical-devices/overview-device-regulation/bioresearch-monitoring. These regulations and guidance are amenable to construction by the court of the terms of the agreement. These numerous resources are intended to assure that to the extent feasible study data are collected per the Protocol, that failure to collect data properly are corrected immediately, to assure the safety of enrolled patients and the corresponding risk-benefit approved by the local IRB, and, overall to assure the quality and integrity of the data to be submitted to FDA.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 27 of the Complaint that RCRI's contractual obligations are set forth in the MSA, which is an integrated agreement, as set forth in section 12.8 thereof, and that any and all additional obligations Physeon seeks to introduce are excluded from the parties' agreement. No contractual terms have been identified by Physeon that might require "construction by the court." Covance accordingly denies all other and further allegations

contained in Paragraph 27 of the Complaint.

28. As part of the MSA, RCRI again represented to Physeon that it is in the business of assisting medical device manufacturers with submissions to domestic and overseas regulatory agencies, clinical trial design, regulatory compliance, management and analysis of data from clinical trials, preclinical study design, having technical procedures and standards for conducting, managing, monitoring, auditing, and identifying and correcting issues during the conduct of the study (commonly identified as "quality systems") and compliance, health economics and outcomes research, and continuing education and training.

**ANSWER:** The MSA speaks for itself, and Covance denies all allegations and inferences that are contrary to the MSA, which is an integrated agreement, as set forth in section 12.8 thereof.

29. The MSA required RCRI to provide to Physeon services as set forth in Work Orders that were to be entered into by and between Physeon and RCRI.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 29 of the Complaint that section 1.1 of the MSA provides that "RCRI agrees to provide [Physeon] the consulting services set forth in detailed work orders ('Work Orders') executed by RCRI and [Physeon] ('Services') using the format, or a format substantially similar to the format, attached [to the MSA] as Schedule 1." Section 1.2 of the MSA further provides that "Each Work Order hereunder shall refer to and be part of this Agreement and shall be governed by the terms and provisions hereof, in

addition to the specific details set forth in the Work Order. To the extent any terms or provisions of a Work Order conflict with the terms and provisions of this Agreement, the terms and conditions of this Agreement shall control, except to the extent that the applicable Work Order expressly and specifically states an intent to supersede the Agreement on a specific matter." Section 1.3 of the MSA additionally provides that "Except for the Services described in Work Orders that are accepted by both RCRI and [Physeon], [Physeon] is under no obligation to retain RCRI to provide any services, nor is RCRI under any obligation to provide services to [Physeon]." Covance denies the allegations of Paragraph 29 of the Complaint to the extent they seek to impose obligations greater or different from those set forth in the MSA and the executed Work Orders.

30. On or about March 26, 2018, Physeon and RCRI executed a Work Order pursuant to which RCRI was to provide "Regulatory, Health Economics, and Clinical Trial consulting support to Physeon GmbH as detailed in the Preliminary Project Estimate titled Integrated Solution for Regulation, Health Economics & Clinical Trial Support for the Veinplicity® Device" project (the "Estimate"). See Work Order attached as Exhibit "3."

**ANSWER:** Covance denies the allegations contained in Paragraph 30 of the Complaint. Covance affirmatively alleges that it executed a Work Order on March 26, 2018, and that Exhibit 3 to the Complaint shows that Kullmann, on behalf of Physeon, executed that Work Order on March 28, 2018. The

Work Order provides, in relevant part, that "RCRI will provide Regulatory, Health Economics and Clinical Trial consulting support to Physeon GmbH for the Veinplicity Device as detailed in the Preliminary Project Estimate titled '*Integrated Solution for Regulatory, Reimbursement, and Clinical Trial Support for the Veinplicity Device*'Version 2 [*sic*], dated 19 March 2018."

31. The Estimate included fees for the entire trial of $310,982.00 for Clinical Trial Support and pass-through costs of $53,922.00 for a total of $364,904.00. Additionally, Regulatory Support fees were estimated at between $20,590 and $27,910.

**ANSWER:** Covance admits the allegations contained in Paragraph 31 of the Complaint.

32. The Clinical Trial Support tasks listed in the Work Order included study initiation, site activation, site management and monitoring, data management, data analysis, clinical reports, and project management and communication tasks. The Work Order and the Estimate budgeted $56,509.00 for site management and monitoring, among other costs. Up to the point where the study was terminated, invoices from RCRI totaled $563,150.96, of which Physeon has paid $473,702.05.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 32 of the Complaint that the clinical trial support tasks listed in the Work Order attached to the Complaint as Exhibit 3 included study initiation, site activation, site management and monitoring, data management, data analysis, clinical reports, and project management and

communication tasks. The Work Order attached to the Complaint as Exhibit 3 and the Estimate budgeted $56,509.00 for site management and monitoring, among other costs. Covance notes that a total of 8 Work Orders were executed and that work was additionally authorized in 1 email. Covance denies the remaining allegations contained in Paragraph 32 of the Complaint and affirmatively alleges that RCRI's invoices totaled $567,176.19 and that Physeon paid $474,308.78, leaving a balance due of $92,867.41.

33. Critically, the Estimate prepared for Physeon by RCRI was based on specific assumptions in regard to each parties' roles and responsibilities with respect to the VIVA Study.

**ANSWER:** Covance admits the allegations contained in Paragraph 33 of the Complaint.

34. RCRI' s assumptions in preparing the Estimate were that it would be responsible for nearly all facets of the VIVA Study itself, including all elements of the Study Initiation, Site Activation, Site Management and Monitoring, Data Management and Data Analysis phases.

**ANSWER:** Covance admits the allegations contained in Paragraph 34 of the Complaint, but also notes that Physeon approved all activities and that, in deviation from assumptions and the parties' agreement, Kullmann performed the device training of study personnel at the Mayo Clinic site and the Regions Hospital site, during which any "5-minute requirement" would have been

included if such a requirement existed. Kullmann further attended the entire training at the Mayo Clinic site and the Regions Hospital site, and would have raised a failure to train regarding a "5-minute requirement" if such a requirement existed. The training materials for all three sites, which Physeon approved, further would have included a "5-minute requirement" if such a requirement existed. Additionally, RCRI did not employ the investigational-site personnel that logistically implemented the clinical study and the investigator(s) at each site contractually bears responsibility to Physeon to adhere to the Protocol.

35. While Physeon was to review portions of the Study Initiation, RCRI was responsible for project start-up and team training, and preparing site training materials, among other responsibilities.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 35 of the Complaint that the responsibility matrix assigns responsibilities and affirmatively states that the matrix assigned to Physeon, and Physeon accepted, significant review responsibilities, including review of site training materials, and that Kullmann performed the device training of study personnel at the Mayo Clinic site and the Regions Hospital site, during which any "5-minute requirement" would have been included if such a requirement existed. Kullmann further attended the entire training at the Mayo Clinic site and the Regions Hospital site, and would have raised a failure to train regarding a "5-minute requirement" if such a requirement

existed. The training materials for all three sites, which Physeon approved, further would have included a "5-minute requirement" if such a requirement existed.

36. RCRI was also solely responsible for the Site Activation phase of the clinical study. RCRI was responsible for investigational site identification, investigational site qualification, investigational site selection, protocol training, budget and clinical trial agreement negotiations, and site set-up support, among other responsibilities, for the VIVA Study.

**ANSWER:** Covance denies the allegations contained in Paragraph 36 of the Complaint. RCRI was not "solely" responsible for site activation and did not "identify the sites." RCRI recommended the Regions and Midwest sites, while Physeon identified the Mayo Clinic site and the lead clinician at the Mayo Clinic (Greg Schears). Physeon later approved the Regions and Midwest sites. RCRI worked with Physeon and the sites to negotiate the clinical trial agreement and budgets, but Physeon was responsible for the approval thereof.

37. RCRI was also solely responsible for the monitoring plan and training, statistical data plan, site initiation visits, interim monitoring visits, study close-out visits, and investigation site management and communication as part of the Site Management and Monitoring portion of the VIVA Study. RCRI was to make four physical or on-site visits to each clinical site during the study for purposes of monitoring and assuring compliance as an adjunct to site communications or monitoring that might

take place via other means, such as phone calls or electronic communications or record-keeping.

**ANSWER:** Covance denies the allegations contained in Paragraph 37 of the Complaint. RCRI estimated the total number of site visits that would be needed, but did not provide a guarantee. Furthermore, RCRI made SQV phone calls and at least 3 in-person visits, when only 1 monitoring visit and 1 close-out visit were included in the proposal, for a total of 2 visits for "monitoring and assuring compliance." Furthermore, RCRI was not "solely" responsible, as set forth in the responsibility matrix. As noted above, Kullmann performed the device training of study personnel at the Mayo Clinic site and the Regions Hospital site, during which any "5-minute requirement" would have been included if such a requirement existed. Kullmann further attended the entire training at the Mayo Clinic site and the Regions Hospital site, and would have raised a failure to train regarding a "5-minute requirement" if such a requirement existed. The training materials for all three sites, which Physeon approved, further would have included a "5-minute requirement" if such a requirement existed.

38. Similar to its responsibility of activating and monitoring the VIVA Study sites, RCRI was also responsible for collecting and managing the clinical data and analyzing it.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 38 of the Complaint that RCRI was responsible for collecting and

managing the clinical data and analyzing it, but denies any incorporated allegation that RCRI was "solely" responsible. Physeon reviewed and approved the data management plan. Furthermore, the data capture systems were created in consultation with Physeon, which was given options regarding data to be captured, with project costs increasing as additional data is captured.

39. In fact, RCRI was responsible for creating the data capture systems for the collection of clinical data resulting from the VIVA Study. RCRI was to prepare the case report forms, which documents are required by FDA to ensure data quality and integrity, and on which the study sites and clinicians would record study data for each patient.

**ANSWER:** Covance admits the allegations contained in Paragraph 39 of the Complaint. Covance additionally notes that the data capture systems were created in consultation with Physeon, which was given options regarding data to be captured, with project costs increasing as additional data is captured.

40. In addition, RCRI was responsible for coordinating and preparing training materials and conducting any necessary training sessions to ensure each clinical site conducted the study in accordance with the Protocol, the informed consent, and the ethical requirements of the institution, and that its clinicians properly enrolled only patents eligible for the study, exposed such patients only to the risks contemplated by the Protocol specified procedures, and its clinicians accurately collected and recorded all VIVA Study data.

**ANSWER:** Covance denies the allegations contained in Paragraph 40 of the Complaint. As noted above, Kullmann performed the device training of study personnel at the Mayo Clinic site and the Regions Hospital site, during which any "5-minute requirement" would have been included if such a requirement existed. Kullmann further attended the entire training at the Mayo Clinic site and the Regions Hospital site, and would have raised a failure to train regarding a "5-minute requirement" if such a requirement existed. The training materials for all three sites, which Physeon approved, further would have included a "5-minute requirement" if such a requirement existed.

41. The data management plan for the VIVA Study, and any associated training with respect to data management, was also RCRI's responsibility.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 41 of the Complaint that it had responsibility for certain data management plan training pursuant to a data management plan that was approved by Physeon. As noted above, Kullmann performed the device training of study personnel at the Mayo Clinic site and the Regions Hospital site, during which any "5-minute requirement" would have been included if such a requirement existed. Kullmann further attended the entire training at the Mayo Clinic site and the Regions Hospital site, and would have raised a failure to train regarding a "5-minute requirement" if such a requirement existed. The training materials for all three sites, which Physeon approved,

further would have included a "5-minute requirement" if such a requirement existed.

42. In addition to Data Management, RCRI was responsible for the Data Analysis phase of the VIVA Study. This included preparing the statistical analysis plan for the VIVA Study, and conducting the Protocol-specified interim statistical analysis and validation, and ultimately the final statistical analysis.

**ANSWER:** Covance denies the allegations as stated in Paragraph 42 of the Complaint and notes that Physeon reviewed and approved the statistical analysis plan. Furthermore, the final statistical analysis was never conducted because Physeon terminated the clinical study.

43. The following table outlines the roles that RCRI and Physeon were to perform with respect to the VIVA Study and the assumptions that RCRI made with respect to the responsibilities of the VIVA study, and relied on in preparing its Estimate, which it ultimately used to invoice Physeon:

## Clinical Study Roles and Responsibilities

The following table outlines the assumptions regarding the roles and responsibilities for the clinical study. These assumed assignments have contributed to the preliminary estimate.

X=Responsible R=Review A=Approve N/A=Not Applicable

| RESPONSIBILITY | | STUDY INITIATION |
|---|---|---|
| Physeon | RCRI | |
| X | X | Project Start-up and Team Training |
| R | X | Clinical Protocol |
| R | X | Informed Consent Form Template |
| R | X | Nondisclosure Agreement Template |
| R | X | Budget and Clinical Trial Agreement Template |
| R | X | Site Training Materials |
| N/A | N/A | Investigator Meeting |
| N/A | N/A | Subject Recruitment Tools/Materials |
| RESPONSIBILITY | | SITE ACTIVATION |
| Physeon | RCRI | |
| | X | Investigational Site Identification |
| | X | Nondisclosure Agreement Negotiation |
| | X | Investigational Site Qualification |
| X | X | Investigational Site Selection |
| | X | Budget and Clinical Trial Agreement Negotiation |
| | X | Informed Consent Form Negotiation |
| | X | Site Set-up Support |
| | X | Regulatory Binder Assembly and Distribution to Site & Sponsor |
| RESPONSIBILITY | | SITE MANAGEMENT & MONITORING |
| Physeon | RCRI | |
| R | X | Monitoring Plan and Training |
| | X | Site Initiation Visits |
| | X | Interim Monitoring Visits |
| | X | Study Close Out Visits |
| | X | Investigational Site Management and Communication |
| N/A | N/A | Electronic Trial Master File (Regulatory Binder) |
| X (payments) | X (reports) | Site Payments |
| RESPONSIBILITY | | DATA MANAGEMENT (with EDC) |
| Physeon | RCRI | |
| R | X | Case Report Form Content |
| R | X | System Edit Check Specifications |
| | X | Database Development and Validation |
| X | X | User Acceptance Testing |
| | X | EDC Training Materials |
| | X | EDC Training Sessions |
| | X | Database Hosting/Usage, Help Desk and Support |
| | X | Database Maintenance and Support |
| | X | Database Lock(s), Data Transfer(s), and Archive |
| X | X | Client Communication/Meetings Regarding Study Database |
| R | X | Data Management Plan and Training |
| | X | Ongoing Data Review & Query Management |
| N/A | N/A | Medical Coding |

| RESPONSIBILITY | | SAFETY MANAGEMENT |
|---|---|---|
| Physeon | RCRI | |
| N/A | N/A | Safety Management Plan and Training |
| N/A | N/A | Safety Management Tasks |
| RESPONSIBILITY | | DATA ANALYSIS |
| Physeon | RCRI | |
| X | | Sample Size Calculation |
| | X | Randomization Schedule |
| | X | Statistical Analysis Plan |
| | X | Statistical Report Shell |
| | X | Statistical Code Development & Validation |
| N/A | N/A | Annual Statistical Analysis & Validation |
| | X | Interim Statistical Analysis & Validation |
| | X | Final Statistical Analysis & Validation |
| X | X | Client Communication/Meetings Regarding Data Analysis |
| RESPONSIBILITY | | CLINICAL REPORTS |
| Physeon | RCRI | |
| N/A | N/A | Annual Clinical Report Development & Validation |
| N/A | N/A | Interim Clinical Report Development & Validation |
| R | X | Final Clinical Report Development & Validation |
| X | X | Client Communication/Meetings Regarding Clinical Reports |
| RESPONSIBILITY | | PROJECT MANAGEMENT & COMMUNICATION |
| Physeon | RCRI | |
| X | X | Project Team Meetings with Client |
| X | X | Project Management and Client Communication |
| | X | RCRI (CRO) Internal Team Meetings |
| | X | Project Files Transfer and Archive |
| N/A | | CLINICAL EVENTS COMMITTEE (CEC) |
| N/A | | DATA SAFETY MONITORING BOARD (DSMB) |
| N/A | | CORE LABORATORY |
| N/A | | INVESTIGATOR MEETING PLANNER |
| N/A | | PUBLICATION PLANNING &SUPPORT |
| N/A | | AUDITS |

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 43 of the Complaint that the table or responsibility matrix accurately displays an initial set of clinical study roles and responsibilities, and denies that Paragraph 43 contains the final version of the responsibility matrix. On June 10, 2019, the responsibility matrix was modified. Generally speaking, safety review and management activities and reporting were

transferred from Physeon to RCRI. Additionally, review of payment information was added.

44. As a result, RCRI and Physeon both understood their roles and responsibilities associated with the VIVA Study. In addition, Physeon and Mary Kay Sobcinski, Senior Principal Advisor-Clinic Studies, of RCRI, held weekly, Monday conference calls throughout the duration of the study. Physeon and RCRI regularly discussed the parties' respective clinical study roles and responsibilities during these calls, which were at all times consistent with the Estimate assumptions above. These conference calls also provided RCRI with the opportunity to report any adverse events or any violations of the Protocol that occurred at the three clinical sites, to Physeon. At no time during those calls did RCRI report that there were any issues with Protocol compliance at any of the study sites.

**ANSWER:** Paragraph 44 of Plaintiff's Complaint violates the requirement of Fed. R. Civ. P. 8(d)(1) that "[e]ach allegation must be simple, concise, and direct." Without waiving that objection, Covance denies that "RCRI and Physeon both understood their roles and responsibilities associated with the VIVA Study" as Physeon did not appear to understand its role or responsibilities. Physeon deviated at times from the roles and responsibilities outlined in the MSA, the responsibility matrix, and the Work Orders. Covance admits that "Physeon and Mary Kay Sobcinski, Senior Principal Advisor-Clinic Studies, of RCRI, held weekly, Monday conference calls throughout the duration of the study," but those calls mostly related to

enrollment and budget issues. Covance denies all other and further allegations.

45. The Work Order and the Estimate also included services for FDA Pre-Submission Preparation and for a Pre-Submission Teleconference.

**ANSWER:** With respect to the allegations contained in Paragraph 45 of the Complaint, Covance admits that the initial Work Order includes FDA pre-submission preparation and a pre-submission teleconference (if needed). However, there were 8 Work Orders.

46. Prior to Physeon's scheduled pre-submission meeting with the FDA on September 4, 2018, Rachel Kennedy, Senior Principal Advisor-Regulatory, and Mary Kay Sobcinski, both of RCRI, provided regulatory support to Physeon and assisted with Physeon's pre-submission preparations, which included authoring Veinplicity® for Improved Venous Access: The VIVA Trial Investigational Plan (the "Investigational Plan" or "Protocol").

**ANSWER:** With respect to the allegations contained in Paragraph 46 of the Complaint, Covance admits that RCRI provided regulatory support to Physeon, but notes that Physeon had material contact with the FDA before engaging RCRI. Covance further admits that it authored "Veinplicity for Improved Venous Access: The VIVA Trial" but denies that it did so alone and affirmatively alleges that Physeon had material involvement in its development as set forth in the responsibility matrix. Covance notes that that the Protocol is deliberately titled "Investigational Plan." Physeon's pre-

RCRI history of FDA interaction is detailed in Q172161S001, including copies of previous deficiency letters. The S001 denotes supplement status, as the interaction was in process before RCRI was engaged.

47. RCRI was responsible for authoring the Investigational Plan. Specifically, Mary Kay Sobcinski took ownership over authoring and finalizing the Investigational Plan. As the author of the Investigational Plan, RCRI would provide drafts of the Investigational Plan to Physeon for review and input.

**ANSWER:** With respect to the allegations contained in Paragraph 47 of the Complaint, Covance admits that RCRI authored "Veinplicity for Improved Venous Access: The VIVA Trial" but denies that it did so alone and affirmatively alleges that Physeon had material involvement in its development and that the Protocol is deliberately titled "Investigational Plan." Covance denies that Ms. Sobcinski is the "owner" of the Investigational Plan or Protocol. Under FDA regulations, an Investigational Device Exemption ("IDE") is the responsibility of the study sponsor: Physeon. Furthermore, RCRI did not "own" any of Physeon's study materials

48. Rachel Kennedy and Mary Kay Sobcinski (of RCRI) also participated in a telephone conference with members of the FDA to discuss Physeon's and RCRI's plan for the VIVA clinical trial. This discussion with the FDA was done to confirm that the Investigational Plan, if successful, would support an application for marketing authorization in the United States.

**ANSWER:** Covance denies the allegations contained in Paragraph 48 of the Complaint. Not only did no telephone call ever take place and were all communications with the FDA in writing, but the allegations confuse a successful investigational plan with a successful application for marketing authorization, while the two are not identical. For an investigational plan to be successful, the acquisition and analysis of the data must be accurate. That same data and analysis may show that an experimental therapy or device does not have the desired effects, yielding a failure for purposes of FDA approval and marketing.

49. Based on these discussions and the FDA's comments, RCRI was aware that compliance with the Investigational Plan was of utmost importance both to Physeon and the FDA, and that the Investigational Plan, if successfully conducted and yielding favorable data on safety and effectiveness of the Veinplicity® device, would adequately support marketing authorization in United States.

**ANSWER:** Covance denies the allegations contained in Paragraph 49 of the Complaint.

50. Mary Kay Sobcinski, as the owner of the Investigational Plan, was also responsible for RCRI's Investigational Plan training, including at each of the three clinical sites.

**ANSWER:** Covance denies the allegations contained in Paragraph 50 of the Complaint. Ms. Sobcinski is not the "owner" of the Investigational Plan or Protocol. Under FDA regulations, an IDE is the responsibility of the study sponsor: Physeon. Furthermore, RCRI did not "own" any of Physeon's study

materials. Physeon reviewed and approved the training materials and, as noted above, Kullmann performed the device training of study personnel at the Mayo Clinic site and the Regions Hospital site, during which any "5-minute requirement" would have been included if such a requirement existed. Kullmann further attended the entire training at the Mayo Clinic site and the Regions Hospital site, and would have raised a failure to train regarding a "5-minute requirement" if such a requirement existed. The Physeon-approved training materials for all three sites further would have included a "5-minute requirement" if such a requirement existed.

51. According to the VIVA Study's Investigational Plan and Work Order, RCRI would serve as the Study Management Center for the trial and would investigate clinical site qualifications prior to a clinic's recruitment into the study. RCRI was also to provide site training to ensure investigational plan compliance as well as accurate data collection, and was to provide a study monitoring plan consistent with the applicable FDA regulations, the Protocol, HIPAA, the IRB rules, the informed consent, and RCRI's standard operating procedures. See Investigational Plan, attached as Exhibit "2."

**ANSWER:** Covance denies the allegations contained in Paragraph 51 of the Complaint. Furthermore, and as noted above, Kullmann performed the device training of study personnel at the Mayo Clinic site and the Regions Hospital site, during which any "5-minute requirement" would have been included if such a requirement existed. Kullmann further attended the entire

training at the Mayo Clinic site and the Regions Hospital site, and would have raised a failure to train regarding a "5-minute requirement" if such a requirement existed. The training materials for all three sites, which Physeon approved, further would have included a "5-minute requirement" if such a requirement existed.

52. As part of the monitoring plan, each study site was to undergo monitoring visits to be conducted by RCRI. These visits, among other things, were to ensure the study site was conducting the study per Protocol, accurately recording data, completing the data forms in a timely manner, and complying with the Investigational Plan. Additionally, RCRI was responsible for providing a qualified and trained site monitor.

**ANSWER:** With respect to the allegations contained in Paragraph 52 of the Complaint, Covance admits that each study site was to undergo monitoring visits to be conducted by RCRI as part of the monitoring plan and that the visits were to review compliance with the Protocol. Covance further admits that RCRI was responsible for providing a qualified and trained site monitor. Covance denies the remaining allegations.

53. In addition to the Investigational Plan, RCRI and Physeon entered into a Statistical Analysis Plan ("Statistical Plan") on or about December 18, 2018. The Statistical Plan was authored by Jenna MacDonald, MS, of RCRI, who signed the Plan on RCRI's behalf. Physeon also agreed to the Statistical Plan.

**ANSWER:** Covance admits the allegations contained in Paragraph 53 of the

Complaint, except that Physeon reviewed and approved the statistical plan and did not merely "agree" with it.

54. The Statistical Plan was based on and included information specific to the Investigational Plan, and required RCRI to collect specific data endpoints. Under the Statistical Plan, RCRI was to review, summarize and analyze the data endpoints as part of its final analysis. RCRI was also required to provide Physeon with an interim, sample size re-estimation analysis that would determine whether the study would continue as originally designed or whether the total study sample size would be increased.

**ANSWER:** With respect to the allegations contained in Paragraph 54 of the Complaint, Covance denies that the statistical plan specifies which data is to be collected, as that information is set forth in the Protocol. Furthermore, the final statistical analysis was never conducted because Physeon terminated the clinical study. Covance admits the remaining allegations.

55. Specifically, RCRI was to ensure that the clinical sites recorded and measured the total procedure time, the change in the vein quality score, and the time to first-stick vein access and success. After the first-stick success rate of approximately the first 58 subjects enrolled in each group (control and Veinplicity®), RCRI was to complete an analysis to determine whether the VIVA Study at interim, completed and carried out pursuant to the Investigational Plan, had a conditional power that was favorable, promising, or sufficiently unfavorable that completion of the study might be reconsidered by Physeon.

**ANSWER:** With respect to the allegations contained in Paragraph 55 of the Complaint, Covance denies that the statistical plan dictates what the clinical sites have to do, as that information is set forth in the Protocol. Covance admits that each study site was to undergo monitoring visits to be conducted by RCRI and that the visits were to review compliance with the Protocol. Covance further admits that RCRI was required to complete, and did complete, a conditional-power analysis and that it provided that analysis to Physeon on July 3, 2019. Covance denies the remaining allegations.

56. The FDA has explained the importance of interim analyses:

> When trial data are examined in a comparative interim analysis, data analyses that were not prospectively planned as the basis for adaptations may unexpectedly appear to indicate that some specific design change (e.g., restricting analyses to some population subset, dropping a treatment arm, adjusting sample size, modifying the primary endpoint, or changing analysis methods) is ethically important or might increase the potential for a statistically significant final trial result. For example, unexpected lack of treatment adherence in one arm of a multiple-arm trial might motivate dropping that treatment arm.

*Adaptive Designs for Clinical Trials of Drugs and Biologics Guidance for Industry*, U.S. Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), November 2019 Biostatistics, at 23.

**ANSWER:** With respect to the allegations contained in Paragraph 56 of the Complaint, Covance denies that the quote is complete, as it omits the final two sentences of the paragraph. In full, the quote reads:

> When trial data are examined in a comparative interim analysis, data analyses that were not prospectively planned as the basis for adaptations may unexpectedly appear to indicate that some specific design change (*e.g.*, restricting analyses to some population subset, dropping a treatment arm, adjusting sample size, modifying the primary endpoint, or changing analysis methods) is ethically important or might increase the potential for a statistically significant final trial result. For example, unexpected lack of treatment adherence in one arm of a multiple-arm trial might motivate dropping that treatment arm. Such revisions based on non-prospectively planned analyses can create difficulty in controlling the Type 1 error probability and in interpreting the trial results. Sponsors are strongly discouraged from implementing such changes without first meeting with FDA to discuss the changes being considered, provided patient safety is not compromised.

Additionally, Covance notes that the material quoted from was not produced by the FDA's Center for Devices and Radiological Health that regulates devices, such that the quote's applicability is questioned.

**"D. Key Requirements And Features Of The Clinical Trial Protocol"**

57. Pursuant to the Investigational Plan, the study sites and clinicians providing treatment with Veinplicity® were required to make the first and, if necessary, the second cannulation attempt "within 5 minutes of stimulation cessation" from the device.

**ANSWER:** Covance denies the allegations contained in Paragraph 57 of the Complaint.

58. The Investigational Plan, therefore, required that the first and second attempts to cannulate a patient's vein be completed within 5 minutes of cessation of Veinplicity® stimulation on a patient's forearm.

**ANSWER:** Covance denies the allegations contained in Paragraph 58 of the Complaint.

59. The Investigational Plan at page 18 further stated the parameters of the administration of the device and the protocol for carrying out the clinical trial as:

> In summary, Veinplicity® stimulation is to be administered only once to each arm; however, both arms may be stimulated sequentially if necessary. Cannulation attempts in an arm must be completed within 5 minutes of stimulation cessation in that arm. An individual clinician can only make up to 2 total attempts at cannulation, and the subject can only have up to 4 total attempts between both arms.

(emphasis added.)

**ANSWER:** Covance denies the allegations contained in Paragraph 59 of the Complaint. Pages 16 and 17, not 18, of the Protocol provide that:

1. The clinician is to remain with the subject during and after stimulation. Refer to the Veinplicity Instructions for Use (IFU) for complete information.
2. Place the Veinplicity electrodes on the selected arm for cannulation. Place the white electrode patch on the palmar surface of the hand and the blue electrode patch on the bicep of the arm (Figure 2). Electrodes can be placed in any orientation as long as the location is maintained. Connect the electrodes to the stimulator using the main cable.
3. Turn Veinplicity on by turning the dial to #1 and observing for a physical response (muscle fasciculation). If muscle fasciculation is not observed, steadily increase the intensity by turning the dial to the maximum level comfortably tolerated by the subject. The subject will experience tingling but the sensation should not be painful. If the sensation is not tolerable, the intensity must be lowered by turning the dial down to a tolerable level that still produces muscle fasciculation.
4. Maintain this intensity for a minimum of 2 minutes and a maximum of 10 minutes, until the target vein becomes visible or palpable. Turn the device off by rotating the dial

counter-clockwise until the on/off light turns off.

5. The site's standard cannulation procedure, i.e., skin cleansing and tourniquet application, is performed. Apply the tourniquet to the same arm that was stimulated with Veinplicity; re-assess and document vein quality poststimulation and record this value on the Procedure Worksheet, then proceed with cannulation.
6. One clinician may make up to two attempts at cannulation. If cannulation is not achieved (flashback obtained and successfully flushed with 3 mL of normal saline without swelling) after two attempts, a second clinician will replace the first and up to two more attempts may be made. ***All attempts on one arm should be made within 5 minutes of stimulation cessation.***
7. If the clinician elects to switch to the other arm to attempt cannulation, Veinplicity must be reapplied to the second arm as described in steps 1-5 above. The same set of electrodes used on the first arm are to be used again on the second arm; do not use a new set of electrodes.
8. If the subject is successfully cannulated (flashback obtained and able to flush with 3 mL normal saline without swelling) in 4 or fewer total attempts, i.e. four attempts total between both arms, the subject is considered to be a success for this study. If the subject is not successfully cannulated (no flashback obtained and/or unable to successfully flush with 3 mL normal saline) in 4 or fewer total attempts between both arms, they are considered to be a study failure and alternative methods of achieving IV access may be used.
7. After declaration of study success or failure, remove the electrodes.
8. Clean and disinfect Veinplicity after each subject as per the instructions for Use.

In summary, Veinplicity stimulation is to be administered only once to each arm; however, both arms may be stimulated sequentially if necessary. ***Cannulation attempts in an arm must completed within 5 minutes of stimulation cessation in that arm.*** An individual clinician an only make up to 2 total attempts at cannulation, and the subject can only have up to 4 total attempts between both arms to determine study success or failure.

(Emphasis added.) The 5-minute statement in the summary sentence was

introduced by Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, but, contrary to the premise of this action, no 5-minute requirement was ever imposed by Physeon. Section 7.2.7 of the Protocol never provided for collection of the time from the end of electrical stimulation to first-stick success/failure, and the primary efficacy endpoint does not restrict patients to those in whom the alleged 5-minute temporal period was satisfied. Furthermore, Physeon's materials boast that "Engorged veins remain palpable for 10 to 30 minutes after stimulation, allowing practitioners to use both hands to gain venous access":


This 10- to 30-minute period is believed to be based on a clinical study performed in the United Kingdom by Andrew Barton for Physeon. Additionally, neither Physeon's instructions for use of the Veinplicity®

device, expressly referred to in the Protocol, nor the Dutch study refer to a 5-minute requirement, and introducing a 5-minute requirement in the United States clinical study would have severely limited the marketability of the Veinplicity® device.

60. RCRI, and specifically Mary Kay Sobcinski, the owner of the Investigational Plan, were well aware that all cannulation attempts in an arm were to be completed within five minutes. During a conference call with Physeon and RCRI to finalize the Investigational Plan, the importance of the 5-minute time limit between the end of stimulation and end of cannulation was discussed in detail, with Mary Kay Sobcinski being very particular about this aspect of the Investigational Plan. In fact, Mary Kay Sobcinski was adamant about including the five-minute cannulation requirement (hereinafter, "5-Minute Requirement") so there could be no misinterpretation about how the protocol was to be followed. She and RCRI knew it was critical to the success of the VIVA Study.

**ANSWER:** Covance denies the allegations contained in Paragraph 60 of the Complaint, and specifically denies the existence of a "5-minute requirement." The 5-minute statement in the summary sentence was introduced by Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, but, contrary to the premise of this action, no 5-minute requirement was ever imposed by Physeon. Furthermore, Ms. Sobcinski is not the "owner" of the Investigational Plan or Protocol. Under FDA regulations, an IDE is the responsibility of the study

sponsor: Physeon. RCRI also did not "own" any of Physeon's study materials and, as noted above, Kullmann performed the device training of study personnel at the Mayo Clinic site and the Regions Hospital site, during which any "5-minute requirement" would have been included if such a requirement existed. Kullmann further attended the entire training at the Mayo Clinic site and the Regions Hospital site, and would have raised a failure to train regarding a "5-minute requirement" if such a requirement existed. The training materials for all three sites, which Physeon approved, further would have included a "5-minute requirement" if such a requirement existed. See also the answer to Paragraph 59.

61. The Investigational Plan also required the completion of data forms, otherwise known as procedure worksheets or case report forms, for all subjects in the clinical trial. For all trial subjects, the following data points were to be recorded:

a) Total procedure time, time from starting skin preparation for the control arm or time from electrode application for the treatment arm, to declaration of the study success/failure for the primary endpoint.

b) Time for tourniquet application after randomization to the time of vein access success/failure declaration from the primary endpoint.

And for the Veinplicity® subject group, the following data was to be collected:

a) Time the first Veinplicity® electrode is applied to the subject's arm to the time of vein access success declaration for the primary endpoint.

b) Time the Veinplicity® device turned on to the time it is turned off (stimulation duration). If Veinplicity® is switched from one arm to the other, mark the time from the second time it is turned on to the second time it is turned off.

c) Stimulation intensity (dial setting(s)); treatment group only.

**ANSWER:** With respect to the allegations contained in Paragraph 61 of the Complaint, Covance admits that section 7.2.7 of version 1 of the Protocol attached to the Complaint provides:

> **7.2.7 Procedure Measurements**
>
> The following data points will be collected on the Procedure Worksheet:
>
> 1. All subjects:
>    a. Total procedure time: time from starting skin preparation for the control arm or time from electrode application for the treatment arm, to declaration of study success/failure for the primary endpoint.
>    b. Time from tourniquet application after randomization to the time of vein access success/failure declaration for the primary endpoint.
> 2. Veinplicity group only:
>    a. Time the first Veinplicity electrode is applied to the subject's arm to the time of vein access success declaration for the primary endpoint.
>    b. Time the Veinplicity device is turned on to the time it is turned off (stimulation duration). If Veinplicity is switched from one arm to the other, mark the time from the second time it is turned on to the second time it is turned off.
>    c. Stimulation intensity (dial setting(s)); treatment group only.

Notably, the Protocol was updated 5 times such that the final version was version 6, and at no time did Physeon require in section 7.2.7 that data be collected about the time between turning off the Veinplicity® device to the time of vein access success/failure declaration for the primary endpoint.

62. The Investigational Plan also set forth additional protocol requirements for the

clinicians treating the patients enrolled in the VIVA Study. To comply with the Investigational Plan, the clinician was to maintain stimulation intensity using Veinplicity® in the Veinplicity® subject group for a minimum of 2 minutes and a maximum of 10 minutes, until the target vein became visible or palpable, before performing the cannulation. First stick, or second stick, must be completed within five minutes. This feature was critical to the principles underlying the regulations applicable to informed consent. A Protocol is approved by an IRB based on the anticipated risks — which would include the duration of electrical stimulation — being outweighed by the potential benefits, including the greater first-stick success rate. Patients who are undergoing the risk, even minimal risk, of device application with little or no, or reduced, likelihood of success consequent to delayed cannulation put the study's IRB approval at risk. Maintaining Protocol compliance is integral to clinical research and an underlying basis for regulations and rules governing such research and, in part, the purpose of monitoring the clinical sites.

**ANSWER:** With respect to the allegations contained in Paragraph 62 of the Complaint, Covance denies that "First stick, or second stick, must be completed within five minutes. This feature was critical to the principles underlying the regulations applicable to informed consent."

63. According the Protocol, the sample size of the clinical trial was to be approximately 246 subjects and the trial was to be completed at up to five study sites in the United States.

**ANSWER:** Covance admits the allegations contained in Paragraph 63 of the

Complaint, and affirmatively alleges that the number of sites subsequently set at three, as set forth in the "pass-through costs" section on page 2 of the Work Order Form attached to the Complaint as Exhibit 3 ("Database Hosting/Usage, Help Desk, Support 3 sites; 400 subject; 10 eCRFs per subject; 40,000 total datapoints; randomization module; 4 months.").

64. Ultimately, three study sites were selected to participate in the VIVA Study. The sites included the Mayo Clinic in Rochester, Minnesota; the Midwest Immunology and Infusion Center in Plymouth, Minnesota; and Regions Hospital in St. Paul, Minnesota.

**ANSWER:** Covance admits the allegations contained in Paragraph 64 of the Complaint.

65. On July 3, 2019, after the first half of the patients had participated in the trial, RCRI sent a written notice to Physeon confirming that there was "no need to increase the sample size of the VIVA trial." Physeon interpreted this notice to mean that the interim analysis had determined that the study had achieved "favorable" statistical significance in the first half of the trial, and so no increase in patient numbers was required prior to completion of the clinical study. However, on July 12, 2019, RCRI provided Physeon with data upon on its request showing the first half of the trial had been determined to be "unfavorable" pursuant to the Statistical Plan. Because RCRI informed Physeon that the study had failed, without discovering and/or disclosing that the unfavorable outcome was based on RCRI's own failure to follow the Investigational Plan, as well as other failures of RCRI in study performance and

conduct, Physeon agreed to shut down the study and stop enrollment.

**ANSWER:** With respect to the allegations contained in Paragraph 65 of the Complaint, Covance admits that Stephanie Guggisberg, an RCRI Independent Advisor and Senior Biostatistician, sent an email on July 3, 2019, to Alan Wilson at Novintum Medical Technology GmbH, Physeon's parent corporation, and to Kullmann, attaching a memorandum. The memorandum stated, full:

RCRI®

5353 Wayzata Boulevard, Suite 505
Minneapolis, MN 55416-1334
Phone: 952-746-8080
Fax: 952-884-6518

# Memo

**To:** Patrick Kullmann, Physeon CEO
**From:** Stephanie Guggisberg
**CC:** Mary Kay Sobcinski
**Date:** 03JUL2019
**Re:** VIVA Trial Study Sample Size Re-Estimation Results

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Dear Mr. Kullmann,

The sample size re-estimation for the VIVA trial has been performed in accordance with the study's Statistical Analysis Plan v2 dated 12 December 2018 and is based on a database archive taken 03JUL2019. There is no need to increase the sample size of the VIVA trial.

Sincerely,

Stephanie Guggisberg
RCRI Independent Advisor and
Senior Biostatistician
sguggisberg@rcri-inc.com



Covance cannot speak to what "Physeon interpreted this notice to mean," and accordingly denies and puts Plaintiff to its strict proof thereof, but notes that

the sample size is not directly correlated to a uniquely positive or negative outcome of the clinical trial, such that any conclusions about "success" or "failure" of the trial based on the July 3, 2019, memorandum would have been objectively unreasonable. Covance further admits that on July 12, 2019, RCRI provided Physeon with data upon Physeon's request, showing the first half of the trial had been determined to be "unfavorable" pursuant to the Statistical Plan and that Physeon shut down the study and stopped enrollment. Covance denies the remaining allegations and specifically denies the existence of a "5-minute requirement," the allegation that RCRI or the clinics "failed to follow the Investigational Plan," and the allegation that RCRI otherwise failed "in study performance and conduct."

66. Physeon's agreement and decision to shut down the study was solely based on the fact that RCRI advised Physeon that it was unlikely that the Study would prove successful should it be completed (including with an increased sample size). Further patient enrollment in the VIVA Study was not needed because RCRI had deemed the study a failure, apparently based on its failure to monitor the study sites to ensure compliance with the Protocol and its failure to report non-compliance to Physeon, which then resulted in a flawed, interim statistical analysis.

**ANSWER:** With respect to the allegations contained in Paragraph 66 of the Complaint, Covance cannot speak to Physeon's motivating factors and accordingly denies and puts Plaintiff to its strict proof thereof. Covance denies that RCRI failed "to monitor the study sites to ensure compliance with

the Protocol" and failed "to report non-compliance to Physeon, which then resulted in a flawed, interim statistical analysis." Covance admits that the statistical data did not suggest that increasing the sample size would improve the outcome.

67. After being shown that the analysis was in error and the conduct of the VIVA Study flawed, Physeon asked RCRI to propose solutions to remedy RCRI's failure to meet its contractual obligations.

**ANSWER:** With respect to the allegations contained in Paragraph 67 of the Complaint, Covance admits that Physeon presented certain information at a September 3, 2019, meeting, denies that it had the opportunity to review or analyze the information, denies that it has any information that RCRI's analysis was flawed or "in error," denies that RCRI's "conduct of the VIVA Study" was "flawed," admits that Physeon made demands that RCRI refund the sums Physeon had paid, admits that Physeon demanded that RCRI re-do the study at RCRI's cost, and denies that RCRI failed to meet its contractual obligations.

**"E. RCRI Failed To Properly Train and Monitor the Clinical Investigators, Failed to Ensure That The Clinical Trial Protocol Was Followed, and Failed to Collect Required Data And Failed To Report Shortcomings To Physeon"**

68. Pursuant to the Statistical Plan and Investigation Plan, RCRI provided an overview and interim, statistical analysis to Physeon after approximately 61 patients had reached the data primary end point, measuring first-stick success, in the Veinplicity® subject group.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 68 of the Complaint that power calculation was performed, but denies that a full statistical analysis was performed because Physeon terminated the clinical trial.

69. Based on the analysis provided by RCRI, the Veinplicity® group had a first attempt success rate of 73% versus a control group (tourniquet only) success rate of 78%. These results, indicating that the VIVA Study was unfavorable, were unexpected, of great surprise to Physeon and significantly different from the results of the prior, published Netherlands Study of Veinplicity®.

**ANSWER:** With respect to the allegations contained in Paragraph 69 of the Complaint, Covance admits that "based on the analysis provided by RCRI, the Veinplicity® group had a first attempt success rate of 73% versus a control group (tourniquet only) success rate of 78%." Covance cannot speak to Physeon's subjective reactions to the data and accordingly denies and puts Plaintiff to its strict proof thereof. A comparison to the Dutch clinical study is invalid because that clinical trial was performed on different study subjects and under a different protocol. The FDA's clinical study standards for Veinplicity® were materially different and more difficult to meet than the standards employed in the Dutch study. The entire purpose of the United States clinical trial was to determine whether Veinplicity® performed as intended under the FDA's more demanding standards.

70. In Physeon's earlier trial in the Netherlands, the Veinplicity® treatment group had

an overall first attempt success rate of 92% and the control (tourniquet) group had a 78% first attempt success rate. Thus, as between the two studies, the control groups were identical at 78%, but the Veinplicity® success rate fell by 19% from the Netherlands Study to the VIVA Study.

**ANSWER:** With respect to the allegations contained in Paragraph 70 of the Complaint, Covance states that it has reviewed the article referenced in Paragraph 13 of the Complaint, but does not have access to the underlying data, such that it cannot confirm or deny the actual data being cited by Physeon and accordingly denies and puts Plaintiff to its strict proof thereof. Covance denies that Physeon's attempt to draw a parallel between the Dutch clinical trial and the United States clinical trial is valid, because the Dutch clinical trial was performed on different study subjects and under a different protocol. The FDA's randomized clinical study standards for the Veinplicity® device were materially different and more difficult to meet than the standards employed in the non-randomized Dutch study. The entire purpose of the United States clinical trial was to determine whether Veinplicity® performed as intended under the FDA's more demanding standards. Because the standards were different, any comparison between the Dutch study and the United States study is invalid. Furthermore, as also stated above, the medical science and epidemiologic literature has copious examples of markedly different trial results when nonrandomized trials on a given therapy are compared to those of randomized trials. Biases inherent in

nonrandomized trials are discussed in Clinical Trial references (*see, e.g.*, Non-Randomized Trial, Zhengqing Li, 14 December 2007, available with subscription at https://doi.org/10.1002/9780471462422.eoct306).

71. As a result of RCRI's interim, statistical analysis, Physeon asked RCRI to provide Physeon with information regarding its training and monitoring of the clinical investigators for the VIVA Study, compliance with the Investigational Plan, and collection and analysis of patient and study data and data on other endpoints.

**ANSWER:** With respect to the allegations contained in Paragraph 71 of the Complaint, Covance admits that Physeon asked RCRI to provide Physeon with information, affirmatively alleges that it provided Physeon the requested information, and denies all other and further allegations contained therein.

72. Among other things, and based on analysis of some of the initial data provided by RCRI and in follow-up thereto, Physeon asked RCRI to provide Physeon with procedure-related data on the length of the interval between the end of stimulation with Veinplicity® and end of the first-stick for the trial subjects, i.e., compliance with the 5-Minute Requirement.

**ANSWER:** With respect to the allegations contained in Paragraph 72 of the Complaint, Covance admits that Physeon asked RCRI to provide Physeon with information, affirmatively alleges that it provided Physeon the requested information, and denies all other and further allegations contained therein, specifically denying the existence of a "5-minute requirement."

Covance affirmatively alleges, as also set forth in its answer to Paragraph 59 of the Complaint, that the 5-minute statement in the summary sentence on page 17 of the Protocol was introduced by RCRI's Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, but, contrary to the premise of this action, no 5-minute requirement was ever imposed by Physeon. Section 7.2.7 of the Protocol never provided for collection of the time from the end of electrical stimulation to first-stick success/failure, and the primary efficacy endpoint does not restrict patients to those in whom the alleged 5-minute temporal period was satisfied. Furthermore, as also stated in Covance's answer to Paragraph 59 of the Complaint, Physeon's materials boast that "Engorged veins remain palpable for 10 to 30 minutes after stimulation, allowing practitioners to use both hands to gain venous access," neither Physeon's instructions for use of the Veinplicity® device, expressly referred to in the Protocol, nor the Dutch study make reference to a 5-minute requirement, and introducing a 5-minute requirement in the United States clinical study would have severely limited the marketability of the Veinplicity® device.

73. RCRI provided the requested data for the 61 patients enrolled in the clinical trial that were within the VIVA Veinplicity® group. For one of the enrolled patients, there was no data available at all. For another, the time to success was documented as negative three (3) minutes. Of the remaining 59 patients, 16 patients (27% of patients enrolled in the Veinplicity® group) did not have the first-stick attempt

completed within 5-minutes of cessation of use of Veinplicity® as required by the Investigational Plan.

**ANSWER:** With respect to the allegations contained in Paragraph 73 of the Complaint, Covance admits that Physeon asked RCRI to provide Physeon with information, affirmatively alleges that it provided Physeon the requested information, and denies the existence of a "5-Minute Requirement." Covance affirmatively alleges, as also set forth in its answer to Paragraphs 59 and 72 of the Complaint, that the 5-minute statement in the summary sentence on page 17 of the Protocol was introduced by RCRI's Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, but, contrary to the premise of this action, no 5-minute requirement was ever imposed by Physeon. Section 7.2.7 of the Protocol never provided for collection of the time from the end of electrical stimulation to first-stick success/failure and the primary efficacy endpoint does not restrict patients to those in whom the alleged 5-minute temporal period was satisfied. Furthermore, as also stated in Covance's answer to Paragraphs 59 and 72 of the Complaint, Physeon's materials boast that "Engorged veins remain palpable for 10 to 30 minutes after stimulation, allowing practitioners to use both hands to gain venous access," neither Physeon's instructions for use of the Veinplicity® device, expressly referred to in the Protocol, nor the Dutch study make reference to a 5-minute requirement, and introducing a 5-minute requirement in the United States

clinical study would have severely limited the marketability of the Veinplicity® device.

74. Perhaps more remarkably, six (6) patients did not have the first attempt even started within 5-minutes of cessation of use of Veinplicity® as required by the Investigational Plan. In fact, the first cannulation attempt on four of these six patients took place 12 or more minutes after the completion of the application of Veinplicity®. Not surprisingly, cannulation was not successful in any of these four patients.

**ANSWER:** With respect to the allegations contained in Paragraph 74 of the Complaint, Covance admits that Physeon asked RCRI to provide Physeon with information, affirmatively alleges that it provided Physeon the requested information, and denies the existence of a "5-Minute Requirement." Covance affirmatively alleges, as also set forth in its answer to Paragraphs 59, 72, and 73 of the Complaint, that the 5-minute statement in the summary sentence on page 17 of the Protocol was introduced by RCRI's Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, but, contrary to the premise of this action, no 5-minute requirement was ever imposed by Physeon. Section 7.2.7 of the Protocol never provided for collection of the time from the end of electrical stimulation to first-stick success/failure and the primary efficacy endpoint does not restrict patients to those in whom the alleged 5-minute temporal period was satisfied. Furthermore, as also stated in Covance's answer to

Paragraphs 59, 72, and 73 of the Complaint, Physeon's materials boast that "Engorged veins remain palpable for 10 to 30 minutes after stimulation, allowing practitioners to use both hands to gain venous access," neither Physeon's instructions for use of the Veinplicity® device, expressly referred to in the Protocol, nor the Dutch study make reference to a 5-minute requirement, and introducing a 5-minute requirement in the United States clinical study would have severely limited the marketability of the Veinplicity® device.

75. A post-study sub-analysis performed by Physeon on the data provided by RCRI on July 19, 2019 showed, however, that when the 5-Minute Requirement in the Investigational Plan was followed by the study site, there was an 87% rate of success within the Veinplicity® subject group.

**ANSWER:** With respect to the allegations contained in Paragraph 75 of the Complaint, Covance admits that Physeon presented certain information to RCRI at a September 3, 2019, meeting, denies that it had the opportunity to review or analyze the information, and denies the existence of a "5-Minute Requirement." Covance affirmatively alleges, as also set forth in its answer to Paragraphs 59, 72, 73, and 74 of the Complaint, that the 5-minute statement in the summary sentence on page 17 of the Protocol was introduced by RCRI's Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, but, contrary to the premise of this action, no 5-minute requirement was ever imposed by Physeon. Section 7.2.7 of the

Protocol never provided for collection of the time from the end of electrical stimulation to first-stick success/failure and the primary efficacy endpoint does not restrict patients to those in whom the alleged 5-minute temporal period was satisfied. Furthermore, as also stated in Covance's answer to Paragraphs 59, 72, 73, and 74 of the Complaint, Physeon's materials boast that "Engorged veins remain palpable for 10 to 30 minutes after stimulation, allowing practitioners to use both hands to gain venous access," neither Physeon's instructions for use of the Veinplicity® device, expressly referred to in the Protocol, nor the Dutch study make reference to a 5-minute requirement, and introducing a 5-minute requirement in the United States clinical study would have severely limited the marketability of the Veinplicity® device.

76. The physiological effect of electrical stimulation following Veinplicity® application is time dependent, with veins returning to their baseline gradually after use. The VIVA Study data showed a correlation between the delay attempt times and first-stick success rates — highlighting why the Protocol was clear as to the 5-Minute Requirement. Again, RCRI was well aware of the 5-Minute Requirement and, in fact, was adamant that it be specifically included in the Investigational Plan.

**ANSWER:** With respect to the allegations contained in Paragraph 76 of the Complaint, Covance lacks information regarding the actual correlation between the physiological effect of electrical stimulation following Veinplicity® application and time and denies the existence of a "5-Minute

Requirement." Covance affirmatively alleges, as also set forth above, that the 5-minute statement in the summary sentence on page 17 of the Protocol was introduced by RCRI's Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, and that, contrary to the premise of this action, no 5-minute requirement was ever imposed by Physeon. Section 7.2.7 of the Protocol never provided for collection of the time from the end of electrical stimulation to first-stick success/failure and the primary efficacy endpoint does not restrict patients to those in whom the alleged 5-minute temporal period was satisfied. Furthermore, as also stated above, Physeon's materials boast that "Engorged veins remain palpable for 10 to 30 minutes after stimulation, allowing practitioners to use both hands to gain venous access" and neither Physeon's instructions for use of the Veinplicity® device, expressly referred to in the Protocol, nor the Dutch study make reference to a 5-minute requirement.

77. As discussed with RCRI before the VIVA study began, adherence to the 5-Minute Requirement in the Investigational Plan was critical to the VIVA Study's success and, of course, the very reason why the Requirement was in the Protocol in the first place. The 5-Minute Requirement was additionally required by the MSA and Work Orders, and RCRI was aware of its importance with respect to Physeon being able to provide reliable and documented efficacy and safety data to the FDA for marketing approval purposes.

**ANSWER:** Covance denies the allegations contained in Paragraph 77 of the

Complaint.

78. Post-study interviews with VIVA Study clinical sites by Physeon in the presence of RCRI personnel, including the investigator at Mayo Clinic, confirmed that RCRI largely failed to educate and train the study sites and their clinicians on the 5-Minute Requirement and that it was repeatedly violated.

**ANSWER:** Because the allegations contained in Paragraph 78 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 78 of the Complaint.

79. In fact, the Mayo Clinic informed Physeon and RCRI during a September 3, 2019, phone call that the RCRI Monitor for the VIVA Study was aware of non-compliance with the 5-Minute Requirement during the pendency of the VIVA Study, but had taken no corrective action at its study site. RCRI also took no action to correct the non-compliance with the 5-Minute Requirement at the other two clinical sites.

**ANSWER:** Because the allegations contained in Paragraph 79 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 79 of the Complaint.

80. Indeed, when RCRI submitted its first interim monitoring report for the Mayo Clinic site, the site monitor reported that "[s]tudy procedures [had been]

performed/documented as required" and no "protocol deviations" had been found. Ultimately, neither of those statements was accurate.

**ANSWER:** Because the allegations contained in Paragraph 80 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 80 of the Complaint.

81. Because the VIVA Study was unblinded, RCRI's monitoring plan should have immediately discovered the high incidence of protocol non-compliance and the impact of non-compliance with the Investigational Plan on the study's results. In fact, the very first patient randomized to the Veinplicity® arm of the study (patient number 01 003), had delayed first-stick in violation of the 5-Minute Requirement. The patient's first attempt took 8.5 minutes after cessation of stimulation with Veinplicity® and the second attempt 10 minutes after cessation of stimulation.

**ANSWER:** With respect to the allegations contained in Paragraph 81 of the Complaint, the use of the term "unblinded" in the context of this clinical study is ambiguous. Because the remaining allegations contained in Paragraph 80 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 81 of the Complaint.

82. RCRI's monitoring of the VIVA Study sites and the clinical trial also should have identified the study sites' failure to properly and timely record time entries on the data forms as required by the Investigational Plan. While RCRI obtained authorization to purchase better timing equipment for the study sites and clinicians — because RCRI claimed study conduct warranted the additional expense to ensure study documentation — RCRI apparently never reviewed data forms nor took any steps to correct this non-compliance.

**ANSWER:** Because the allegations contained in Paragraph 82 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 82 of the Complaint. Furthermore, the log of edit checks and deviations constructed by RCRI demonstrate that the monitoring plan was implemented. Additionally, both sets of timers were selected and purchased by Physeon, not by RCRI.

83. Had RCRI reviewed the data forms, the study sites' non-compliance with both entering data and in complying with the 5-Minute Requirement as clearly set forth in the Investigational Plan would have been obvious. The failure to do so was in breach of the MSA, Work Order and the Investigational Plan as well as state, institutional and federal regulations governing clinical trials — to which RCRI had committed to adhere in those self-same documents.

**ANSWER:** Because the allegations contained in Paragraph 83 of the

Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 83 of the Complaint.

84. As a self-proclaimed "leading clinical research organization," RCRI should have known that its failure to ensure the Investigational Plan was followed would result in unreliable and unusable results, no matter the outcome, and Physeon being left with unusable data with respect to future FDA submissions. Indeed, FDA audits clinical sites for study protocol compliance before accepting any data for review, and data collected in abeyance of such compliance is deemed invalid by FDA regardless of the success or failure of the study.

**ANSWER:** Because the allegations contained in Paragraph 84 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 84 of the Complaint.

85. RCRI also should have known that the interim analysis should account for instances where the Investigational Plan was not followed, which apparently was commonplace during the VIVA Study as monitored by RCRI. Aside from the ethical impropriety of enrolling and treating patients outside the Protocol parameters, patients in whom the physiological effect has functionally dissipated should not be included in an interim assessment designed solely to consider whether

the device is likely to work as a predicate to Physeon's decision of whether to finish the study.

**ANSWER:** Because the allegations contained in Paragraph 85 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 85 of the Complaint. Covance affirmatively alleges, as also set forth in its answer to Paragraphs 59 and 72 and other Paragraphs of the Complaint, that the 5-minute statement in the summary sentence on page 17 of the Protocol was introduced by RCRI's Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, but, contrary to the premise of this action, no 5-minute requirement was ever imposed by Physeon. Section 7.2.7 of the Protocol never provided for collection of the time from the end of electrical stimulation to first-stick success/failure and the primary efficacy endpoint does not restrict patients to those in whom the alleged 5-minute temporal period was satisfied. Furthermore, as also stated above, Physeon's materials boast that "Engorged veins remain palpable for 10 to 30 minutes after stimulation, allowing practitioners to use both hands to gain venous access," neither Physeon's instructions for use of the Veinplicity® device, expressly referred to in the Protocol, nor the Dutch study make reference to a 5-minute requirement, and introducing a 5-minute requirement in the United States

clinical study would have severely limited the marketability of the Veinplicity® device. Furthermore, and as set forth with respect to Paragraph 19, *supra*, any suggestion that a sub-analysis may be performed, such as Physeon claims to have performed after July 12, 2019, is in direct conflict with the biostatistical principle of analysis per "Intention to Treat." The handpicking of data after the fact in an attempt to find the best possible outcome is considered unscientific and is discredited by the scientific community. Thus, the FDA's Centers for Drug Evaluation and Research (CDER) and Biologics Evaluation and Research (CBER) have warned that "[p]reservation of the initial randomization in analysis is important in preventing bias and in providing a secure foundation for statistical tests." E9 Statistical Principles for Clinical Trials (Sept. 1998) (ICH) (copy available at https://www.fda.gov/media/71336/download). Accordingly, section 9.4.1 of the Protocol specifically provides that an "Intent to Treat" approach will be used for statistical analyses that will include all randomized subjects.

86. Had RCRI identified in the interim analysis the lack of Protocol adherence, it is probable that it could have adjusted the study such that the findings of the study as a whole would have reached statistical significance, rather than dooming Veinplicity®'s promising future.

**ANSWER:** Because the allegations contained in Paragraph 86 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or

allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 86 of the Complaint. Covance affirmatively alleges, as also set forth in its answer to Paragraphs 59, 72, and other Paragraphs of the Complaint, that the 5-minute statement in the summary sentence on page 17 of the Protocol was introduced by RCRI's Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, but, contrary to the premise of this action, no 5-minute requirement was ever imposed by Physeon. Section 7.2.7 of the Protocol never provided for collection of the time from the end of electrical stimulation to first-stick success/failure and the primary efficacy endpoint does not restrict patients to those in whom the alleged 5-minute temporal period was satisfied. Furthermore, as also stated above, Physeon's materials boast that "Engorged veins remain palpable for 10 to 30 minutes after stimulation, allowing practitioners to use both hands to gain venous access," neither Physeon's instructions for use of the Veinplicity® device, expressly referred to in the Protocol, nor the Dutch study make reference to a 5-minute requirement, and introducing a 5-minute requirement in the United States clinical study would have severely limited the marketability of the Veinplicity® device. Covance submits that any statement about a "promising future" is mere speculation and accordingly denies the same and puts Plaintiff to its strict proof thereof.

87. As a result of RCRI's failure to properly train the VIVA Study clinical sites and its

investigators and clinicians, failure to properly manage and monitor the clinical trial of the Veinplicity® device, and failure to properly manage and analyze the clinical data, Physeon's VIVA Study was fundamentally undermined and rendered worthless.

**ANSWER:** Covance denies the allegations contained in Paragraph 87 of the Complaint. Specifically, Covance denies that RCRI failed to "properly train the clinical sites and its investigators and clinicians," that it failed to "properly manage and monitor the clinical trial of the Veinplicity® device," that it failed to "properly manage and analyze the clinical data," and that the clinical trial was "fundamentally undermined." Physeon's own CEO did the site trainings at the Mayo Clinic and at Regions Hospital and did not educate the clinics about a 5-minute requirement.

88. In addition, RCRI's failure to properly analyze the data and provide Physeon with complete and accurate case report forms and interim statistical analysis resulted in RCRI prematurely, and wrongfully, declaring the VIVA Study a failure. Based on RCRI prematurely declaring the VIVA Study a failure, the VIVA Study was prematurely closed to the harm of Physeon.

**ANSWER:** With respect to the allegations contained in Paragraph 88 of the Complaint, Covance denies that RCRI failed to provide Physeon with all the data requested by Physeon; that RCRI "prematurely, and wrongfully, declar[ed] the VIVA Study a failure"; and that Physeon was harmed by any actions or inactions of RCRI, if it was harmed at all.

**"F. Harm To Physeon And The Veinplicity® Device"**

89. Physeon was unaware of the irregularities that were occurring during the course of the VIVA Study. RCRI did not provide information with regard to its breaches of the MSA and the Work Order, or RCRI's failure to follow the Investigational Plan. Because the interim analysis included patients treated outside the bounds of the Investigational Plan, without identifying the fact that those patients were treated outside the Protocol, the conclusions drawn from the interim analysis were flawed.

**ANSWER:** Because the allegations contained in Paragraph 89 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 89 of the Complaint. Covance specifically denies that there were "irregularities" during the course of the clinical trial, that RCRI breached the MSA or any other contractual obligation or regulatory or compliance rule and that RCRI failed to follow the Investigational Plan. Covance further denies that patients were treated "outside the bounds of the Investigational Plan," and that any analysis was "flawed." Covance affirmatively alleges, as also set forth in its answer to Paragraphs 59 and 72 and other Paragraphs of the Complaint, that the 5-minute statement in the summary sentence on page 17 of the Protocol was introduced by RCRI's Mary Kay Sobcinski in an attempt to standardize the procedures between the three study sites, but, contrary to the premise of this

action, no 5-minute requirement was ever imposed by Physeon. Section 7.2.7 of the Protocol never provided for collection of the time from the end of electrical stimulation to first-stick success/failure and the primary efficacy endpoint does not restrict patients to those in whom the alleged 5-minute temporal period was satisfied. Furthermore, as also stated above, Physeon's materials boast that "Engorged veins remain palpable for 10 to 30 minutes after stimulation, allowing practitioners to use both hands to gain venous access," neither Physeon's instructions for use of the Veinplicity® device, expressly referred to in the Protocol, nor the Dutch study make reference to a 5-minute requirement.

90. Because of RCRI's breaches and other wrongdoings, the data acquired from the VIVA Study cannot be used reliably or for the intended purpose, which was to provide reliable data on the safety and efficacy of Veinplicity® in relation to the end points of the clinical trial for the purposes of submission to relevant regulatory authorities, namely the FDA. Further, had the study been performed in compliance with the Protocol, the available data would result in a conclusion that the Veinplicity® device was safe and effective and Physeon would have had RCRI complete the study. But, based on RCRI's breaches and wrongdoings as described above, that outcome is no longer possible.

**ANSWER:** Covance denies the allegations contained in Paragraph 90 of the Complaint. Specifically, Covance denies that RCRI breached the MSA or any other contractual obligation or regulatory or compliance rule, that RCRI

committed any "wrongdoing" in conjunction with the clinical trial, that the data acquired from the clinical trial is faulty, that the Protocol was not followed, and that the data resulting from following the Protocol would have resulted in a conclusion that the Veinplicity® device was safe and effective. Covance further denies that it is no longer technically possible to perform a clinical trial based on a 5-minute requirement. It was Physeon that directed that the "blind" be broken. It was Physeon that performed an *ad hoc* analysis using a subset of (optimal) patients. And it was Physeon that closed the clinical trial. Physeon performed these activities without consultation with or guidance from the FDA, and any potential loss of value of the clinical trial rests with these critical decisions by Physeon rather than the presentation of a properly blinded power calculation that adhered to the statistical plan.

91. The numerous violations of the Investigation [*sic*] and failure to properly monitor and oversee the clinical trial — in violation of the MSA and Work Order, as well as RCRI's own guidelines and standards, and applicable FDA regulations — have caused the results of the VIVA Study to be of no value. Attempts to use the flawed data to seek marketing authorization in the U.S. from the FDA would be futile.

**ANSWER:** Covance denies the allegations contained in Paragraph 91 of the Complaint.

92. Physeon has therefore suffered damages, including but not limited to the money paid by Physeon to RCRI to conduct the VIVA Study.

**ANSWER:** Covance denies the allegations contained in Paragraph 92 of the Complaint.

**"COUNT I: BREACH OF CONTRACT"**

93. Physeon restates and re-alleges the allegations within the foregoing paragraphs as though set forth fully herein.

**ANSWER:** Covance admits that Physeon restates and re-alleges the allegations of Paragraphs 1 through 92 in Paragraph 93 of its Complaint as though set forth fully therein, and incorporates its responses to each of those Paragraphs as if fully set forth herein.

94. Physeon entered into the MSA with RCRI wherein RCRI agreed to conduct the VIVA Study in accordance with the Work Order, which required RCRI to ensure the Investigational Plan was followed by the study sites and its clinicians through site training, management, and monitoring, including a detailed review of the Investigational Plan. It also required Investigational Plan compliance.

**ANSWER:** Covance admits with respect to the allegations contained in Paragraph 94 of the Complaint that RCRI entered into the MSA attached to the Complaint as Exhibit 1 on March 19, 2018, and affirmatively alleges that Exhibit 1 to the Complaint shows that Kullmann executed the MSA on behalf of Physeon on March 23, 2018. The MSA speaks for itself, and Covance denies all allegations and inferences that are contrary to the MSA, which is an integrated agreement, as set forth in section 12.8 thereof.

95. The MSA is a valid and enforceable written contract.

**ANSWER:** Covance admits the allegations contained in Paragraph 95 of the Complaint.

96. Physeon performed all conditions precedent under the MSA, and made payments totaling 473,702.05 to RCRI.

**ANSWER:** Covance denies the allegations contained in Paragraph 96 of the Complaint and affirmatively alleges that RCRI's invoices totaled $567,176.19 and that Physeon paid $474,308.78, leaving a balance due of $92,867.41.

97. RCRI breached the MSA by failing to provide the site training, management and study site monitoring necessary to ensure the Investigational Plan was followed in the VIVA Study.

**ANSWER:** Covance denies the allegations contained in Paragraph 97 of the Complaint.

98. Specifically, RCRI failed, among other things, to ensure the study sites followed the 5-Minute Requirement as mandated in the Investigational Plan. This resulted in unreliable data, including with respect to vein quality scores.

**ANSWER:** Because the allegations contained in Paragraph 98 of the Complaint depend on the veracity of the assumption or allegation that a 5-minute requirement existed and because such underlying assumption or allegation has been repeatedly denied because it is not supported by the facts, Covance denies the allegations contained in Paragraph 98 of the Complaint.

99. RCRI failed to confirm that the study sites were accurately or thoroughly

completing the case report forms and other VIVA Study documents.

**ANSWER:** Covance denies the allegations contained in Paragraph 99 of the Complaint.

100. RCRI's failures included, but are not limited to, the following:

a) Not providing adequate site training to ensure Investigational Plan compliance, including the full and accurate collection of data;

b) Not implementing a study monitoring plan and quality systems that were both consistent with the applicable FDA regulations and RCRI's standard operating procedures, which would have identified and corrected the Investigational Plan non-compliance.

**ANSWER:** Covance denies the allegations contained in Paragraph 100 of the Complaint.

101. As a result of RCRI's breaches of the MSA and Work Order, the VIVA Study was not conducted according to the Investigational Plan as agreed to by Physeon and RCRI, which both parties understood was critical to success of the clinical trial and the FDA's acceptance of the trial's data on safety and efficacy for Veinplicity® and for marketing approval in the United States.

**ANSWER:** Covance denies the allegations contained in Paragraph 101 of the Complaint.

102. As a direct and proximate result of RCRI's breaches of the contract, Physeon has been damaged and seeks recovery from RCRI of all amounts paid to RCRI under the MSA and Work Order.

**ANSWER:** With respect to the allegations contained in Paragraph 102 of the Complaint, Covance admits that Physeon seeks damages, denies that

RCRI has breached the MSA or any other contractual obligation or regulatory or compliance rule, and denies that RCRI failed to follow the Investigational Plan. Covance further denies that Physeon has been damaged by any action or inaction by RCRI and denies that Physeon is entitled to any recovery from RCRI or Covance.

103. Pursuant Section 12.4 of the MSA, the prevailing party in this action shall be awarded costs and fees, including reasonable attorneys' fees.

**ANSWER:** Covance admits the allegations contained in Paragraph 103 of the Complaint.

104. As a direct and proximate result of RCRI's breaches, Physeon has suffered and will continue to suffer damages.

**ANSWER:** Covance denies the allegations contained in Paragraph 104 of the Complaint.

**"COUNT II — UNJUST ENRICHMENT"**

105. Physeon restates and re-alleges the allegations within the foregoing paragraphs as though set forth fully herein.

**ANSWER:** Covance admits that Physeon restates and re-alleges the allegations of Paragraphs 1 through 104 in Paragraph 105 of its Complaint as though set forth fully therein, and incorporates its responses to each of those Paragraphs as if fully set forth herein.

106. Physeon conferred a benefit on RCRI by, among other things, entering into the MSA and making payments to RCRI.

**ANSWER:** Covance denies the allegations contained in Paragraph 106 of the Complaint, inasmuch as Physeon appears to incorrectly suggest that RCRI's benefit was greater than Physeon's benefit under the MSA. Furthermore, no unjust enrichment cause of action can lie based on a contract, which has been alleged, and is admitted, to exist.[1]

107. RCRI has knowingly accepted the benefit of payments from Physeon for the services provided under the MSA.

**ANSWER:** Covance denies the allegations contained in Paragraph 107 of the Complaint, inasmuch as Physeon appears to incorrectly suggest that RCRI's benefit was greater than Physeon's benefit under the MSA. Furthermore, no unjust enrichment cause of action can lie based on a contract, which has been alleged, and is admitted, to exist.

108. It is unjust and inequitable for RCRI to accept and retain this benefit because it failed to provide to Physeon the contracted-for services.

**ANSWER:** Covance denies the allegations contained in Paragraph 108 of the Complaint. Furthermore, no unjust enrichment cause of action can lie

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[1] *Caldas v. Affordable Granite & Stone, Inc.*, 820 N.W.2d 826, 838 (Minn. 2012) ("Unjust enrichment is an equitable doctrine that allows a plaintiff to recover a benefit conferred upon a defendant when retention of the benefit is not legally justifiable. It is commonly referred to as a quasi-contract or a contract implied-in-law claim. It does not apply when there is an enforceable contract that is applicable." "Unjust enrichment claims do not lie simply because one party benefits from the efforts or obligations of others, but instead it must be shown that a party was unjustly enriched in the sense that the term unjustly could mean illegally or unlawfully." (*citing ServiceMaster of St. Cloud v. GAB Bus. Servs., Inc.*, 544 N.W.2d 302, 306 (Minn. 1996))).

based on a contract, which has been alleged, and is admitted, to exist, nor does Physeon set forth the elements of an unjust enrichment claim in its second cause of action.

109. Physeon has been damaged and seeks recovery of all amounts paid to RCRI under the MSA, and in an amount to be proven at trial.

**ANSWER:** Covance denies the allegations contained in Paragraph 108 of the Complaint. Furthermore, no unjust enrichment cause of action can lie based on a contract, which has been alleged, and is admitted, to exist.

## AFFIRMATIVE DEFENSES

By way of avoidance, and as a precautionary matter and without assuming the burden of proof, which burden Covance asserts is on Plaintiff, Covance sets forth the following affirmative defenses:

1. Plaintiff's claims are barred for failure to comply with Minn. Stat. § 303.20.

2. Plaintiff's Complaint fails, in whole or in part, to state a claim upon which relief can be granted.

3. Plaintiff's claims are barred, in whole or in part, by the parol evidence rule.

4. Plaintiff's claims are barred, in whole or in part, by Kullmann's ratification of the clinic training program by providing that portions of the training and attending the remaining aspects of the training without raising any objections, while the training did not include a "5-minute requirement" component.

5. Plaintiff's claims are barred, in whole or in part, by discharge through RCRI's full

performance under the MSA and Plaintiff's voluntary termination of the clinical trial.

6. Plaintiff's claims are barred, in whole or in part, by discharge through RCRI's full performance under the MSA and Plaintiff's abandonment of the contract, such that RCRI's obligations were satisfied by accord.

7. Plaintiff's claims are barred by Physeon's failure to perform all conditions precedent if, and to the extent, Physeon claims to have desired to include a "5-minute requirement" in the MSA, Protocol, and/or the 8 Work Orders executed by the parties.

8. Plaintiff's claims are barred, in whole or in part, by waiver of remedies pursuant to the parties' MSA, including sections 9.1 and 10 thereof.

9. Plaintiff's unjust enrichment claim is barred, in whole or in part, by the doctrine of unclean hands.

10. Plaintiff's claims are barred, in whole or in part, by the doctrine of *in pari delicto*.

11. Plaintiff has failed to mitigate any damages it may have sustained.

12. To the extent Plaintiff claims that Patrick Kullmann, Physeon's CEO, is a third party, Plaintiff's injuries were caused, in whole or in part, by the acts or omissions of third parties over whom RCRI had no control and for whose acts it was not responsible.

13. To the extent Plaintiff claims that Lori Segar, Physeon's contract Director of Clinical Operations, is a third party, Plaintiff's injuries were caused, in whole or in part, by the acts or omissions of third parties over whom RCRI had no control and

for whose acts it was not responsible.

14. To the extent decisions regarding the contents of the Protocol and decisions to terminate the clinical trial were made by persons outside Physeon, such as by persons employed by Plaintiff's direct or indirect parent companies, Plaintiff's injuries were caused, in whole or in part, by the acts or omissions of third parties over whom RCRI had no control and for whose acts it was not responsible.

**COUNTERCLAIM – BREACH OF CONTRACT**

As and for its Counterclaim for breach of contract against Plaintiff Physeon GmbH ("Physeon"), Covance Inc. ("Covance") states and alleges as follows:

1. Covance is the successor in interest by merger to Regulatory & Clinical Research Institute, Inc. ("RCRI").

2. RCRI and Physeon entered into a Master Services Agreement, a copy of which Plaintiff filed in this action at Docket No. 6 (the "MSA").

3. Pursuant to the MSA, Plaintiff agreed to pay RCRI certain sums, as set forth in the MSA and in a total of 8 Word Orders executed by Physeon and RCRI at various times.

4. Plaintiff further authorized $3,860 of work in a July 10, 2019, email from Patrick Kullmann to Mary Kay Sobcinski.

5. RCRI invoiced Physeon the sum of $567,176.19.

6. Physeon paid RCRI the sum of $474,308.78.

7. To date, Physeon has failed and refused to pay the balance due of $92,867.41.

8. Pursuant to section 12.4 of the MSA, the prevailing party in this action shall be awarded its costs and fees, including reasonable attorneys' fees.

9. Through its Counterclaim, Covance seeks the recovery of the $92,867.41 that Physeon to date has failed and refused to pay, as well as the recovery of its attorneys' fees and costs.

10. This Court has diversity jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a) because there is complete diversity of citizenship between all parties and the amount in controversy exceeds $75,000, exclusive of interest and costs.

11. Specifically, Covance is a Delaware corporation with its principal place of business in New Jersey, making it a citizen of Delaware and New Jersey for diversity purposes

12. Physeon is a Swiss company with a principal place of business in Schaffhausen, Switzerland, making it a citizen of Switzerland for diversity purposes.

13. Venue is proper in this federal district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this district.

14. Venue and personal jurisdiction are further proper in this federal district because section 12.4 of the MSA provides for personal and exclusive jurisdiction and venue in Minnesota.

15. Section 12.4 of the MSA further provides that it shall be governed, enforced, and construed by Minnesota law without giving effect to the principles of conflicts laws thereof.

16. The MSA is a valid and binding agreement.

17. The 8 Work Orders entered into by the parties are valid and binding agreements.

18. Physeon's CEO, Patrick Kullmann, was authorized to commit Physeon to pay RCRI the sum of $3,860 for work to be performed by RCRI as set forth in a July 10, 2019, email chain between Mr. Kullmann and RCRI's Mary Kay Sobcinski.

19. RCRI performed all of the work it committed to do pursuant to the MSA, the 8 Work Orders, and the July 10, 2019, email chain.

20. Physeon is currently in breach of its obligations to pay the $92,867.41 balance due to Covance, as successor by merger to RCRI.

21. Covance is entitled to a judgment against Physeon for $92,867.41 plus an award of its attorneys' fees and costs pursuant to section 12.4 of the MSA.

22. Covance is additionally entitled to an award of pre-judgment interest at 10% per annum, pursuant to Minn. Stat. § 549.09.

**PRAYER FOR RELIEF**

WHEREFORE, Defendant Covance Inc. prays for relief as follows:

1. That the Court award Covance judgment in Covance's favor and against Plaintiff on Plaintiff's claims and that the Court dismiss the same with prejudice.

2. That the Court award Covance the sum of $92,867.41 on its Counterclaim, plus pre-judgment interest at 10% per annum, pursuant to Minn. Stat. § 549.09.

3. That the Court award Covance its attorneys' fees, costs, and disbursements pursuant to section 12.4 of the parties' Master Services Agreement.

4. That the Court award Covance all other and further relief deemed just and reasonable.

**JURY DEMAND**

Defendant Covance Inc. hereby demands a trial by jury of all aspects of the case so triable.

DATED: April 10, 2020.

**STOEL RIVES LLP**

*/s/ Marc A. Al*

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